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7.0 UNCERTAINTIES IN RISK ASSESSMENT

The purpose of this baseline risk assessment is to identify areas and activities in the Coeur d'Alene River Basin with potential risks and hazards that are greater than the public health target goals established by the EPA. The findings of the risk assessment will be incorporated into the FS in order to select the most appropriate human health remedies for the COPCs in areas where risks exceed target health goals. Estimating and evaluating health risk from exposure to environmental chemicals is complex process with inherent uncertainties. Uncertainty reflects limitations in knowledge and simplifying assumptions that must be made in order to quantify health risks.

Uncertainty can be statistically classified into four types (Finkel 1990; Hattis and Burmaster 1994): parameter uncertainty, model uncertainty, decision-rule uncertainty, and variability. Of these, the first two often provide much of the overall uncertainty in risk assessment (in contrast to risk management), and provides much of the uncertainty for this HHRA.

Parameter uncertainty includes measurement errors and random and/or systematic errors arising from the inability to measure variables precisely and accurately (equipment and laboratory protocol problems), or because the quantity being measured varies spatially or temporally. Basic methodological (laboratory processing and equipment) errors were less a problem for the data sets included in the Basin HHRA, given the reliance on standardized CLP and other QA/QC-dictated criteria. The principal problems lie more with sampling, i.e., spatial and temporal error.

Spatial and temporal errors apply to both the lead and non-lead sections and to both environmental and exposure biomarker measurements such as blood lead. For brief illustration, the 1996 Basin ATSDR/IDHW study sampled exposure units, particularly residential soils, differently than did the later EPA field work. Geostatistical characterization of the various segments of the Basin was limited, due in no small part to the complex nature of the contaminant point sources. Consequently, point and block kriging or other geostatistical approaches to characterize distributions of contaminants are largely absent and limit the ability to quantify uncertainty in sampling.

Temporal errors are of differing type in the HHRA and include different times for environmental data gathering and blood lead sampling, along with differing sampling designs within separate blood survey efforts. Temporal errors also apply to the extent of any differences arising in the out years, versus the present, in the absence of remedial measures: future land use changes, future exposure receptor demographic and socioeconomic characteristics, etc.

Model uncertainty can arise from use in any model of surrogate variables, from excluded variables that should have been included, abnormal conditions, incorrect model forms, etc. This is of special concern in lead risk assessment, as pathways of lead exposure have both direct effects (from contact with contaminated media) and secondary impacts such as the soil and paint contributions to house dust lead. Failure to correctly specify these variables can lead to uncertainties in interpreting quantitative results.

Abnormal conditions affecting model evaluation can be problematic when using a highly variable exposure measure, such as blood lead, to validate or calibrate exposure models using measured blood lead data. It is always important to characterize the validity of the blood lead data to assure the true reflection of steady-state lead exposures of children and other receptors, and not transitory or abrupt changes.

Decision-rule uncertainty, unlike the first two elements, is more important to the risk manager rather than the risk assessor. Examples include uncertainties within the process of evaluating competing or different priorities among societal and economic concerns when arriving at an acceptable level of measured or modeled risk.

"Variability" is often confused with "uncertainty," but the terms are different. Variability, according to currently accepted risk terminology and methodology, is taken as the underlying and relatively stable distribution of some parameter that can be empirically characterized in knowable biological, physical, bio-physicochemical, or chemical terms. Variability can be characterized empirically in an exposure population, but that does not eliminate its contribution to overall uncertainty. For example, in the case of lead and non-lead contaminants in yard soils, such factors as particle size distribution, chemical species, matrix effects, and so on can be characterized. However, this does not fully resolve uncertainty as to where to sample soil and what to sample.

Uncertainty can be assessed via a formal analysis or can be described qualitatively. The choice of qualitative or quantitative approaches depends on the completeness of the database and the purposes of the original risk analysis. In formal or quantitative analysis, the uncertainty with each parameter in the risk estimation process is first quantified. Uncertainty is described by inclusion of a standard error of means or probability density functions (relative probability for discrete parameter values). Then, numerical methods such as one- or two-dimensional Monte Carlo analyses can be used to develop a composite uncertainty distribution by merging all individual distributions. In this way, the risk or model equations undergo solution repetition using randomly sampled values from the specified distributions to calculate a distribution of risk values. For example, an exposure or risk level for lead can be selected that corresponds to the 95th percentile of the overall risk distribution rather than relying on a single point estimate of risk based on the 95th percentile measures of each parameter.

For the data sets used in this HHRA, "variability" has not been systematically assessed and some question of true representativeness of the sampled populations to the true populations remain within the point estimates. In addition, the overall data base borrows from several underlying studies conducted over a four year period. Given these limitations and the diversity of the data sets in the various Basin studies, uncertainty issues are addressed qualitatively in this HHRA.

Uncertainties reflect limitations in knowledge. In this assessment, uncertainties relate to (*i*) the development of media concentrations that people are exposed to, (*ii*) the assumptions about exposure and toxicity, and (*iii*) the characterization of health risks. Uncertainty in the development of media concentrations is due to the inability to sample every square inch of potentially impacted media at a site. Instead, a limited number of samples must be obtained to represent the contaminant characteristics of a larger medium. The sampling strategies for non-lead contaminants in this assessment were, in general, designed to prevent underestimation of media concentrations, thus avoiding an underestimation of the risks to public health. In the risk assessment, uncertainties were handled conservatively (i.e., health protective choices were preferentially made). Media sampling for lead differed with some of the data sets and it is less likely that underestimations of media lead levels were systematically avoided.

There are uncertainties regarding the quantification of health risks in terms of a number of assumptions about both exposure and toxicity, including both site-specific and general uncertainties. Based on anticipation of uncertainty when quantifying exposure and toxicity, the health risks and hazards presented in this risk assessment are more likely to indicate that chemicals are exceeding target risk goals, although health risks may actually be negligible. Risk assessment methodology is less likely to indicate that chemicals are not a health risk when they actually are. This process is necessary to ensure the protection of public health.

Uncertainty in the risk assessment produces the potential for two kinds of errors. The first potential, or Type I, error is the identification of a specific chemical, area, or activity as a health concern when, in fact, it is not a concern (false positive conclusion). The second potential, or Type II error is the elimination of a chemical, area, or activity from further consideration when, in fact, there should be a concern (false negative conclusion). In the HHRA, uncertainties were handled conservatively (i.e., health protective choices were preferentially made). This strategy is more likely to produce false positive errors than false negative errors.

The following sections provide additional detail regarding uncertainties in the estimations of health risks.

7.1 FACTORS LEADING TO POSSIBLE OVERESTIMATION OF RISK

Assumptions in the risk assessment with the potential to overestimate risk are discussed in the following subsections. These protective assumptions compensate for uncertainties in the calculations or simplifications that might potentially underestimate risk (discussed in Section 7.2).

7.1.1 Data Collection and Evaluation

The data evaluation process addresses whether (1) chemicals are potentially present in various environmental media at levels of health concern, (2) site concentrations are different from background concentrations, and (3) sufficient samples have been collected to fully characterize each exposure pathway.

Soil and Sediment Sampling

Thousands of soil and sediment samples have been collected in the Coeur d'Alene Basin over many years and within a large area. The risk assessment for both lead and the non-lead metals used a subset of the total data available. The HHRA data subset preferentially selected soil samples that were (1) sieved to represent the fine particles that stick to children's hands (less than 175-micron diameter), and (2) collected from places known to be used by people (primarily residential yards and areas with high public use). Where sieved data were unavailable, bulk data that met the risk assessment quality standards were used.

For non-lead metals, 191 homes were sampled and analyzed for non-lead metals. From these homes, 929 soil samples were used in the EPC calculations for residential exposure. The samples used for the residential soil data had all been sieved. All the homes from which soil samples were collected had been volunteered by the residents. It is unknown whether the volunteer aspect of the sampling resulted in an overestimation or underestimation of metal concentrations. For lead, however, nearly half the homes in the Basin were sampled (homes had been volunteered but a concerted effort was made to include as many homes as possible) and no significant differences could be found between the IDHW/ATSDR and EPA data sets for lead. Lead is collocated with the other mining-related metals, i.e., high lead concentrations indicate high concentrations of the other mining-related metals and vice versa (see Appendix F). As a result, the soil data for non-lead metals from the 191 homes are likely representative of the remainder of the Basin.

A total of 49 common use (or public) areas were sampled in the Basin. Common use areas were selected with local input to identify the areas with the highest public use. Of the 49 selected areas, 33 are located along the lower Coeur d'Alene River, 1 is located on Coeur d'Alene Lake (Blackwell Island), and 15 are upland parks, schools, and day care centers in the towns of Silverton and Wallace. This effort to evaluate public areas involved sampling nearly all of the commonly used areas throughout the Basin. A total of 647 soil and sediment samples were collected from public areas for use in the EPC calculations. Concentrations of metals in these areas ranged from relatively low to very high when compared to human health SVs. Therefore, exposure to metals during recreational activities in areas that have not been sampled is unlikely to be underestimated.

In addition to easily accessible public areas, the risk assessment also evaluated "neighborhood" exposure to soil and sediment at undeveloped areas adjacent to homes. As part of the effort to characterize neighborhood exposures, several waste piles near homes in Canyon Creek, Nine Mile Creek, and Mullan that could be accessed by children were sampled. A total of 27 samples were collected from five waste piles for use in the EPC calculations. Waste piles generally have the highest metal concentrations and including them as part of the neighborhood exposures likely resulted in overestimation rather than underestimation of these types of exposure.

Neighborhood sediment concentrations were evaluated in Canyon Creek, Nine Mile Creek, Elk Creek, Pine Creek, and the South Fork. A total of 75 sediment samples from the five water bodies were used in the EPC calculations. While there are a number of additional creeks in the upper Basin with homes adjacent to water, the other creeks are unlikely to have sediment concentrations greater than those in Canyon Creek or Nine Mile Creek, which have some of the largest mining impacts in the area. Therefore, creeks that were not sampled and/or did not have data that were usable in the risk assessment are unlikely to have higher metals concentrations in sediments. In the absence of data, exposure to unsampled creeks should be assumed to be within the range of risks found in the risk assessment and potentially as great as the risks in Canyon Creek and Nine Mile Creek, where risks were greatest (Figures 5-1 and 5-2). However, neighborhood sediment concentrations may be underestimated because the samples were not sieved before analysis (see Section 7.2.1).

Surface Water Sampling

Public exposures to surface water during recreational use were evaluated in the Lower Basin using "disturbed" samples, i.e., samples that were collected after the water had been stirred up. These water samples contained a large amount of suspended sediments. Because water in the lower Coeur d'Alene River typically has a lower suspended sediment load, metal concentrations in water have likely been overestimated. Concentration data from a total of 127 disturbed water samples were used in the EPC calculations.

7.1.2 Exposure Assessment

For estimating the RME, upper 90th percentile values or high-end estimates of national averages are generally used for exposure assumptions. As discussed by the EPA, the intent of the RME is to present risks as a range from CT to high-end risk ("above the 90th percentile of the population distribution") (Habicht 1992). This descriptor is intended to "estimate the risks that are expected to occur in small but definable 'high end' segments of the subject population" (Habicht 1992). The EPA makes a distinction between scenarios that are possible, but highly improbable, and those that are conservative, but more likely to occur within a population, with the latter being favored in risk assessment. RME calculations thus overestimate risk for the majority of a hypothetical population even though all assumptions may not be at their maximum.

The following discussion summarizes exposure assumptions that potentially overestimate risk.

Ingestion of Soil and Sediment

The intake rates of soil and sediment included an assumption that the rates of ingestion of soil and sediment during recreational activities were 300 mg/day for young children, and 100 mg/day for older children and adults. This applied to all chemicals except lead, because different values for ingestion are used in the IEUBK Model for lead. The intake rate of 300 mg/kg day is the 90th percentile value from a study of the amount of soil ingested by children while camping (van Wijnen et al. 1990). The average value from this study was 120 mg/day. Use of the 90th percentile value likely overestimates soil ingestion for the majority of children.

The exposure rates may be exceeded by some individuals within a population. For example, a child on a given day may ingest more than 300 mg or the 200 mg/day assumed for residential exposures. A recent evaluation suggests that the 90th percentile level for the average daily soil ingestion rate may be as high as 1,100 mg/day assuming the variability measured in warmer seasons can be extrapolated over a year (Calabrese and Stanek 1995). The 90th percentile of the average soil ingestion rate during the measurement period was about 180 mg/day (Calabrese and Stanek 1995). The soil ingestion rate is intended to be a daily average over the exposure period, rather than a maximum value, i.e., an actual child may ingest more than 200 or 300 mg one day but less than 200 or 300 mg on other days. Therefore, on average, over the years of the exposure periods, soil ingestion rates will be less than the 90th percentile values; therefore, ingestion will be overestimated for most children.

Averaging Time

The assumption of a 70-year averaging time used in EPA RME assumptions tends to overestimate cancer risks, which are prorated over the lifetime. The current life expectancy in the United States is actually 75.7 years (Bureau of the Census 1994). A 75.7-year averaging time is more consistent with the way the arsenic SF was developed and thus technically should be used in the risk calculations rather than the 70-year default value.

7.1.3 Toxicity Assessment and Risk Calculations

Toxicity values have been developed by the EPA from the available toxicological data. These values frequently involve high- to low-dose extrapolations and are often derived from animal rather than human data. In addition, there may be few studies available for a particular chemical. As the unknowns increase, the uncertainty of the value increases. Uncertainty is addressed by reducing RfDs using uncertainty factors and by deriving SFs using a conservative model. The greater the uncertainty, the greater the uncertainty factors and tendency to overestimate the toxicity.

The risk calculations combine uncertainties regarding the data evaluation, the exposure assessment, and the toxicity assessment.

Arsenic Toxicity Issues

For cancer effects, the conservative assumption is made that some finite risk is associated with exposure to even one molecule of arsenic. EPA SFs are generally based on linear high- to low-dose extrapolations primarily from animal studies. In reality, detoxification reactions in the body may significantly reduce the risk of cancer at low doses (Williams and Weisburger 1996). This may be true for arsenic because the human body has the ability to detoxify arsenic by changing inorganic arsenic to less toxic organic forms that are more readily excreted in urine. Some inorganic arsenic is also directly excreted in the urine. The half-life of ingested arsenic in the body is about 4 days, with urine being the greatest pathway of elimination (NRC 1999). While the human body does appear to detoxify arsenic, primarily by methylation and excretion in the urine, the recent review of arsenic toxicity in drinking water by the National Research Council (NRC) noted that more research is needed on possible differences in arsenic methylation abilities between children and adults (NRC 1999). Children may be a more sensitive population to arsenic's effects (both cancer and noncancer) because they do not detoxify arsenic as well as adults. The report also found a wide variation in methylated forms of arsenic in the urine and recommended more study in this area before drawing conclusions or quantifying detoxification abilities and their effect on health endpoints (NRC 1999). Therefore, it is unknown whether linear high to low extrapolation for arsenic resulted in an SF that overestimates risks.

Other potential sources of uncertainty regarding the arsenic SF are due to unresolved scientific issues regarding differences between the Taiwanese population (including, potentially, their ability to detoxify arsenic) and the U.S. population. The issues have been discussed in numerous reports, including a presentation of issues (Mushak and Crocetti 1995), a detailed response (Slayton et al. 1996), and a rebuttal (Mushak and Crocetti 1996). These differences in the Taiwanese population include their water intake, diet, hygiene, and exposure to other carcinogenic chemicals in drinking water as well as sources of arsenic other than drinking water (arsenic-contaminated water was used for agriculture and aquiculture). The current arsenic SF is based on skin cancer; however, the NRC report found supporting evidence of internal organ cancers in populations in Argentina and Chile exposed to arsenic concentrations similar to those in Taiwan. In terms of diet, Argentina and Chile are more similar to the United States than Taiwan (this issue is discussed further in Section 7.2). The findings regarding internal organs support the current arsenic SF and indicate that it may even underestimate the cancer risks related to internal organs.

Skin cancer was not observed among 145 persons exposed to arsenic in drinking water in Millard County, Utah, at a concentration of 6 µg/kg-day (Southwick et al. 1983; Valberg et al. 1993), which is equivalent to an arsenic soil concentration greater than 15,000 mg/kg. A number of studies did not report any skin cancer below this exposure level (Abernathy et al. 1989; USEPA 1988; ATSDR 1993). However, these studies did not have sufficient statistical power to detect effects if they existed and they did not consider internal organ cancers.

Exposure Scenario Combinations

Combining exposure scenarios would result in higher hazard/risk estimates than presented for individual scenarios in this risk assessment. As an example, hazard/risk results were calculated for a combination of child/adult resident and neighborhood recreational scenarios in Section 5. Combining the two exposure scenarios resulted in more exposure areas with hazard indices higher than 1 and cancer risks higher than 1×10^{-4} than for individual scenarios. Therefore, calculating hazard/risk estimates for individual exposure scenarios could underestimate hazard/risk at the site in cases where combinations of exposures occur.

However, combining scenarios could also result in overestimates of hazard/risk for actual individuals. For example, child/adult residents are assumed to spend 24 hours/day, 350 days/year at their residence. Assuming that residents also regularly spend several hours each day at a neighborhood or public recreational area or also are exposed occupationally at the site results in "double counting" (exposure for more than 24 hours/day), which will overestimate hazard/risk. The combining of exposure scenarios conservatively assumes that the maximally exposed individual for one route and pathway is the same as the maximally exposed individual for all the other routes and pathways.

7.2 FACTORS LEADING TO POSSIBLE UNDERESTIMATION OF RISK

Potential underestimation of risk is always possible because sampling every square inch of a site is technically unfeasible, toxicity data are often incomplete, simplifying assumptions must be made, and all hypothetically possible conditions and pathways cannot be assessed. The protective assumptions presented in Section 7.1 are intended to balance factors that tend to underestimate risk. Some of the potential sources of underestimation are discussed in the following subsections.

7.2.1 Data Collection and Evaluation

Despite extensive sampling of soil, sediment, surface water, and groundwater throughout the Basin, some unsampled areas could have higher or lower concentrations than ones that were sampled.

Surface Water Sampling

Surface water samples were collected from the five water bodies noted in Section 7.1.1 (Elk Creek, Pine Creek, Canyon Creek, Nine Mile Creek, and the South Fork). These samples consisted of undisturbed water, i.e., no special effort was made to stir up the sediment prior to sample collection. Data from a total of 220 samples from these five water bodies were used in the EPC calculations. This data set includes water sample results from high-flow events when the water would be expected to carry an increased load of sediments (early spring runoff from storm events). However, it also includes data from samples collected at low flow. While most of these streams have limited amounts of sediments along the stream channels (unlike the lower Coeur d'Alene River) and recreational use would be expected to be minimal during high-flow events, additional exposure to metals in suspended sediments for individuals during water play in the creeks may be underestimated.

Sediment Sampling

The sediment data used to evaluate the neighborhood exposures for all geographical areas except the Lower Basin came from un-sieved samples, because the samples were not collected specifically for the purposes of the HHRA. Sediment data from sieved samples were not available for these areas. The smaller size fraction of sediment and soil generally has higher concentrations of metals than bulk samples. Therefore, using un-sieved data for neighborhood sediment exposure concentrations likely underestimates the magnitude of exposure for that pathway.

Chemicals Not Selected for Risk Assessment in Soil

Mercury in soil and sediments was screened out from further evaluation in the data evaluation process because its exceedance over the SV would not contribute significantly to site hazards. Approximately 13 percent of the mercury concentrations exceeded the SV with less than 0.1 percent of the concentrations exceeding the residential PRG of 22 mg/kg (10 times the SV). In addition, the few mercury samples with concentrations greater than the residential PRG were all collocated with lead concentrations in excess of 2,000 mg/kg (6 samples out of 4,208 had concentrations greater than the PRG). Thus, soil remediation for lead would be expected to also remove any scattered mercury concentrations over the PRG. Appendix D includes a histogram of mercury concentrations in soil/sediment showing the majority of the concentrations at less than the SV. A UCL_{95} of the mean concentration was less than the SV, indicating that hazards due to mercury in soil would likely be 0.1 or less. Thus, mercury is not a significant contributor to site hazards and its exclusion from the risk assessment does not affect the conclusions of the risk assessment.

Thallium was also not selected as a COPC in soil and sediment. Thallium concentrations showed a pattern similar to that for mercury with concentrations in approximately 13 percent of the samples exceeding the SV and approximately 0.9 percent of the data exceeding the residential PRG. Thallium had the lowest frequency of detection of any metal (16 percent). Approximately 75 percent of the sample quantitation limits for thallium in soil exceeded the SV of 0.52 mg/kg and 0.1 percent (four samples) exceeded the PRG of 5.2 mg/kg. The majority of the sample quantitation limits were less than 2 mg/kg (approximately 80 percent). If thallium concentrations in the four samples with non-detections (sample quantitation limits over the PRG) were actually greater than the PRG, the hazard due to this chemical would not substantially increase. When thallium concentrations in soil and sediment are graphed using half the sample quantitation limit for the non-detected samples, the majority of the data are less than the SV and hazards would be approximately 0.1 or less for residential exposures and less than that for recreational and occupational exposures. If the concentrations in the samples with non-detections were closer to the sample quantitation limits, hazards due to thallium would still be unlikely to exceed 0.2 and, thus, would not have an impact on the results of risk assessment. Consequently, thallium is unlikely to contribute significantly to health hazards even if actual concentrations in the samples with non-detections are just below the sample quantitation limit, rather than the default assumption of half the sample quantitation limit. Thus, the exclusion of thallium from the risk assessment does not affect the conclusions of the risk assessment. Appendix D includes a histogram showing the distribution of thallium concentrations in soil and sediment along with the mean and UCL_{95} of the mean.

Aluminum in soil and sediments was screened out from further evaluation because its concentrations are potentially at background for the area, and no concentrations exceeded the PRG. In addition, aluminum is likely present in a form that is less bioavailable than that used in deriving the provisional RfD. However, the majority of the data in CSM Units 1 and 2 (86 percent and 90 percent, respectively) exceeded the SV and 18 percent of the data exceeded the SV in CSM Unit 3. If aluminum had been included in the risk assessment, it would likely have resulted in HQs between 0.2 and 0.6 for residential soils, which could have an impact on the results of the risk assessment for some exposure scenarios. Aluminum concentrations are likely at or below the background concentrations for northern Idaho. The mean background concentration of aluminum for the western United States is estimated at 58,000 mg/kg, with a range of 5,000 to 100,000 mg/kg (Shacklett and Boerngen 1984). The maximum concentration in soil samples collected in the Basin was 52,000 mg/kg. Although quantifying aluminum exposures would increase hazard estimates, remediation efforts typically do not address chemicals that are present at background concentrations. Thus, including aluminum in the risk assessment would not affect ultimate risk management decisions.

7.2.2 Exposure Assessment

Exposure Factor

Estimates of exposure duration are based on best estimates of what exposures will be. If work or recreational patterns include more time in contaminated areas than the amount estimated, the current exposure estimates may underestimate actual exposure for the occupational and recreational scenario (exposures for the residential scenario assume all time is spent at the home).

Individuals within a population may have higher exposure rates than assumed by the separate exposure assumptions. However, the RME values used represent the maximum exposures that could reasonably be expected to occur in the population.

Under RME conditions, individuals are expected to be exposed to the Upper Confidence Limit of the mean concentration of chemicals for 30 years. Some individuals may live in the area for longer than 30 years.

Complete Pathways Excluded From Evaluation

Not all possible pathways were quantified. Potentially complete pathways that were not selected for quantification include inhalation; ingestion of beef, wild fowl, game, or berries from the lower floodplain; and dermal contact with water (all metals) and soil (all metals except arsenic and cadmium). Some of the exposure pathways in the floodplain of the Lower Basin are discussed further in the paragraphs below. In general, excluding these pathways is assumed not to affect the conclusions of the risk assessment because where metals are the chemicals of concern, the soil ingestion pathway is always the main component determining site risk (Glass and SAIC 1992; USEPA 1995b; Weston 1995, 1996b).

Ingestion of Local Beef. Local residents who eat locally raised beef are the population of concern for this pathway because beef purchased on the open market is typically not from only one source. Most individuals consume beef from cattle raised in a location other than their immediate community; thus, consumption of beef from local cattle will not contribute significantly to total exposure in the general population. Only 2.4 percent of the total meat consumed in the average U.S. household is from home-raised cattle and only 3.8 percent of the beef eaten in the average household is from home-raised cattle (USEPA 1997a). Because beef from home-raised cattle is consumed by only a small portion of the U.S. population and it constitutes a small percentage of the total diet, this pathway does not significantly contribute to total exposure for the general U.S. population.

Although metals taken up into plant tissue are available for ingestion by beef cattle and other herbivores, most metals are generally present in plant tissues at concentrations that are typically orders of magnitude less than the surrounding soil concentrations. Except for cadmium, these metals do not tend to bioaccumulate in plant tissue. For example, the recommended root uptake factors (ratio of concentration in plant tissue to the concentration in the soil) for arsenic, cadmium, lead, and mercury are 0.0004, 0.04, 0.002, and 0.05, respectively (CalEPA 1996). However, other studies have shown that concentrations of cadmium in some plant tissues are higher than those in surrounding soils (Nwosu, Harding, and Linder 1995), and cadmium was found to be a health hazard for vegetable consumption.

In addition, the amount of soil ingested by cattle while grazing is small, approximately 0.05 percent by weight of the pasture grasses ingested (CalEPA 1996). A study that investigated concentrations of metals in edible beef tissue in comparison to soil concentrations could not be located. However, a conservative calculation (see Appendix J) that assumes 100 percent contaminated cattle forage, 100 percent bioavailability, and no depuration, estimates that a concentration of 2 mg/kg arsenic in soil would result in a concentration of approximately 0.0033 mg of arsenic per kg of fresh edible beef tissue. Assuming conservatively that all meat consumed is contaminated beef, a 70 kg male who consumes 250 g of meat per day would have a dose of 0.000012 mg arsenic/kg body weight-day (CalEPA 1996; USEPA 1990c, 1998a). Calculations using the most health-protective assumptions (as described above) result in some health risks that exceed the target risk goals; however, actual metal concentrations in edible tissue are likely to be lower than the conservative estimate presented here. For example, individuals are unlikely to eat 250 mg/kg of local beef every day for 70 years and the bioavailability of arsenic in soil is unlikely to be 100 percent. If the uncertainty regarding this pathway is a concern, actual tissue samples should be collected from the edible portions of locally raised beef cattle.

Ingestion of Waterfowl and Large Game. Hunting of both waterfowl and large game in the Panhandle region is limited primarily to the fall and early winter (September to mid-December) and takes are restricted depending on the species. Take of most large game is limited to one to two animals per year per permit holder. Take of waterfowl is higher, up to 8 and 14 per year for geese and ducks, respectively. Because of the difference in body size between large game and waterfowl, the total amount of metals consumed by humans is expected to be similar for game and waterfowl. These restrictions limit the amount of game that residents can ingest.

While wildfowl have been studied and are considered no to be a concern for human health (Weston 1989), big game has not been evaluated. Only one muscle tissue sample of white-tail deer from CSM Unit 2 is available (collected by the US Fish and Wildlife Service). While no conclusions can be reached from only one sample, the results of the sample and some conservative risk and hazard estimates are presented below for discussion purposes.

Wet weight concentrations of muscle tissue were calculated from dry weight concentrations assuming 70 percent moisture (default values of non-human mammalian moisture content range from 70 to 80 percent) and using the dry weight-to-wet weight formula presented in Section 3.3.1 for vegetables. Wet weight concentrations for four of the COPC metal are:

Arsenic	0.15 ppm
Cadmium	0.19 ppm
Mercury	0.03 ppm
Lead	1.17 ppm

To estimate risks and hazards we used an ingestion rate for game corrected for body weight of 0.446 g/kg-day, the 99th percentile rate from USEPA (1997a), and the same formulas used to calculate doses from vegetables (Table 4.3 in Appendix A). Under those assumptions, hazards from arsenic, cadmium, and methyl mercury are estimated at 0.2, 0.08, and 0.1, respectively. Arsenic risks are 4 x 10^{-5}, assuming all arsenic is in the inorganic form, a very conservative assumption. Thus, risks and hazards from this one sample do not appear to be a large concern and would not add significantly to the total residential risks and sample to not appear to be a large concern and would not add significantly to the total residential risks and hazards in the Basin. However, one sample and a default exposure formula are insufficient to either include or exclude and exposure pathway. The deer was not collected from the area with the most contaminated soils (CSM Unit 3) and it is not known if the deer grazed in that area. Therefore, this pathway remains an uncertainty, is a potential source of metals for hunters, and may warrant further investigation.

7.2.3 Toxicity Assessment and Risk Calculations

Bladder and Lung Cancer From Ingested Arsenic

After an extensive review of available literature, the NRC report evaluating health risks from arsenic in drinking water concluded that in addition to the previously documented risk of skin cancer, there is sufficient evidence to link ingested arsenic with bladder and lung cancer (NRC 1999). Increased rates of bladder and lung cancer have been observed in humans who ingest arsenic in drinking water containing several hundred µg/L. While it is unknown what happens at lower doses, the NRC concluded that the evidence is insufficient to depart from the default assumption of a linear relationship (using EPA criteria in USEPA 1996e). The NRC report estimated that combined cancer risks due to drinking arsenic at the MCL of 50 µg/L might be as high as 1 in 100, an order of magnitude greater than the risk of skin cancer by itself (NRC 1999). The NRC acknowledges a number of problems with quantifying the dose response relationship for internal organ cancers; however, it recommends lowering the MCL as soon as possible because the current MCL likely does not meet EPA criterion for public health protection (i.e., risks falling within the range of 1×10^{-4} to 1×10^{-6}). Therefore, total cancer risks due to arsenic based on the skin cancer SF could be underestimated if risks from lung and bladder cancer were also considered.

In addition to the strong evidence of lung and bladder cancer associated with ingested arsenic, there is additional evidence from the Taiwanese population of an association between arsenic in groundwater with cancer in other internal organs such as the kidney, liver, and colon (Chen et al. 1985, 1986). A dose-response relationship between arsenic in well water and cancer of the liver, nasal cavity, bladder, kidney, lung and prostate cancer has been reported (Chen and Wang 1990). Studies in Argentina indicated an increase in kidney cancers in addition to skin, lung, and bladder cancers (Hopenhayn-Rich et al. 1996; Hopenhayn, Biggs, and Smith 1998). It is unknown whether the current SF for arsenic protects against these additional types of cancer.

Risks and Hazards Added to Residential Exposures

Risks and hazards due to the ingestion of locally grown vegetables and local fish were not combined with other risk/hazards in the risk and hazard totals presented in Section 5. The RME hazard indices for eating cadmium in fish ranged from 0.005 to 0.02 indicating that an increase in hazards from cadmium in fish is unlikely to affect the hazard totals or risk assessment conclusions if added to the residential scenarios. The RME hazard indices for eating mercury in fish were 0.3, 0.9, and 0.6 for bullhead, northern pike, and perch, respectively. If local fishermen eat only bullhead, total hazards for residents would not significantly be affected, if fish ingestion hazards due to methyl mercury were added to residential scenarios. However, for local fishermen who eat primarily northern pike, and secondarily perch, the hazards from eating fish containing methyl mercury could add significantly to residential scenarios at some locations. The mercury concentration in northern pike used in the risk calculations was 0.133 ppm and the value for perch was 0.089 ppm.

The ATSDR (1993) reports for mercury that the average concentration in most fish is less than 0.2 ppm and UCL_{95} mercury concentrations in fish tissue from the lateral lakes are below this value. The highest concentration of mercury in fish from the lateral lakes was a value of 0.48 ppm in northern pike. Average mercury concentrations in perch and pike from the Wabigoon/English/Winnipeg River system in Canada were 0.01 ppm - 0.055 ppm, and 0.04 - 1.2 ppm, respectively (ATSDR 1993). The lateral lakes' mercury concentrations for pike fall within the above range while the concentrations for perch are higher.

The RME hazard index for homegrown vegetables was 2 for child and child/adult residents and the RME cancer risk was 8×10^{-5} for child/adult residents. These values are large enough to significantly affect the hazard/risk estimates for the residential scenario in several exposure areas and could impact the overall conclusions of the risk assessment. However, the vegetable data are considered semi-quantitative because of the non-systematic sampling of gardens and the small data set (e.g., vegetable data were not available for all exposure areas because of opportunistic sampling [see Section 2]). It is unknown how many homes in the Basin have vegetable gardens and whether the homes and vegetables sampled were representative. Cadmium concentrations in leafy and root vegetables in the limited data set appear to be higher by almost an order of magnitude than the national averages, and the concentrations in Basin vegetables are similar to those found in Pinehurst in 1983 (PHD et al. 1986).

Not combining the results for vegetables with hazard/risk estimates for residents may have resulted in an underestimation of hazard/risk for some residents. The magnitude of the underestimation is unknown due to the uncertainty regarding the data set for homegrown vegetables.

7.3 FACTORS LEADING TO POSSIBLE UNDERESTIMATION OR OVERESTIMATION OF RISK

Several factors have the potential to overestimate or underestimate risk. This section discusses these factors and the likely effect of combining uncertainties in evaluating risk.

7.3.1 Data Collection and Evaluation

A risk assessment depends heavily on the quality and representativeness of the sampling data. Uncertainties contributing to sample variation may involve the heterogeneity of the sample matrix (e.g., particle sizes in soil), the number of samples collected in various locations, and the field or laboratory analytical techniques. These sampling uncertainties can underestimate or overestimate risk.

House Dust

The house dust data for the non-lead metals were not used in the EPC calculations for residential exposure primarily because of (1) the lack of sufficient dust data (in six of the eight residential areas fewer than 10 dust samples were available [see Table 3-3]), and (2) the uncertainty associated with the prediction of a dust concentration on the basis of a yard soil concentration. Scatter plots of house dust versus soil (Appendix I) indicate no clear relationship between the concentrations in house dust and yard soil, i.e., as concentrations in soil go up, concentrations in dust do not necessarily increase also and vice versa. Because of the time spent in the house, especially by young children, a significant portion of a child's soil exposure occurs from dust in the home. In the EPA IEUBK Model for lead, the amount of time spent outdoors is assumed to represent 45 percent of the child's day, while 55 percent of the child's exposure occurs indoors (USEPA 1994a). As a result, metal concentrations in indoor dust that are significantly different from concentrations in outdoor soil could make a difference in the EPC and the estimate of risk or hazard.

Two types of house dust samples were collected: dust from floor mats and dust from vacuum cleaner bags. The data from vacuum cleaner bags are considered more representative of dust exposures in the home than data from floor mats, while floor mats provide a better estimate of the total amount of outside soil tracked into the home. Once the soil is in the home, other dust generated inside the home likely dilutes the soil particles (unless there is an in-home source, such as with lead) (Trowbridge and Burmaster 1996). Examples of dust particles generated in the home are flaking skin scales, dust from carpet lint, organic material, and flakes of construction material (Trowbridge and Burmaster 1996). As a result, concentrations of metals in the vacuum cleaner bag samples are expected to be lower than those in outdoor soil because of the dilution of outdoor soil by indoor-generated dust (Trowbridge and Burmaster 1996). Concentrations of metals in floor mat samples are expected to be similar to those in outdoor soil. Iron and manganese were the only two metals that showed the expected pattern—concentrations in outdoor soil samples and floor mat samples were the same and concentrations in vacuum cleaner bag samples were about half those in outdoor soil.

Concentrations of antimony, arsenic, cadmium, and zinc all showed a statistically significant enrichment in floor mat dust when compared to outdoor soil. All but arsenic also showed an enrichment, though not as great, in vacuum bag dust. The results of the paired t-test performed on floor mat and vacuum cleaner bag concentrations versus outdoor soil concentrations are presented in Appendix I. The statistical comparison was performed after the removal of one outlier sample from each of the chemical-specific data sets, with the exception of antimony, which had no outliers. Data were tested for outliers using the studentized residual test performed in SYSTAT *v*.9. For the statistical comparison, the soil data were pooled for each chemical for all the homes with floor mat and vacuum cleaner data and were found to be lognormally distributed. Residential soil data for different geographical subareas presented in the Part D Table 3 series were often not lognormally distributed.

The statistical results indicate that concentration dilution is occurring in the home (vacuum cleaner bags) relative to entry into the home (floor mats); however, the concentrations of all metals, except arsenic and lead, in dust from vacuum cleaner bags exceeded the concentrations in outdoor soil. The reasons for the concentration enrichment are unknown. Possible explanations include the following:

- The mechanisms by which yard soil is being transported into the home preferentially bring in particles smaller than those (less than 175-micron diameter) collected in the yard soil samples. Because samples consisting of smaller particles have higher concentrations of metals, the concentrations in house dust are greater than those in outdoor soil.

- Bias may be introduced by the comparison of results from different sampling methods for house dust and soil.

- There may be sources of outdoor metals entering homes that are not from the yards.

- A potential indoor source of metals is being added to metals tracked in from the yard.

Further investigation is needed to explain the results (e.g. more data gathering, further analysis, etc.). Depending on the chemical and the dust data used, concentrations in house dust could either be the same as those in outdoor soil, less than those in outdoor soil, or greater than those in outdoor soil.

Ratios of chemical concentrations in soil to those in dust from floor mats and vacuum cleaner bags are presented in Table 7-1. Arsenic and iron are the chemicals contributing most to the noncancer hazard in residential homes. Both their concentrations were generally lower in dust from vacuum cleaner bags than in outdoor soil, indicating that EPC concentrations could be overestimated for these metals; however, arsenic concentrations in the floor mat samples were higher than those in outdoor soil. If dust samples from vacuum bags represent the best measure of indoor dust, the use of concentrations to estimate house dust concentrations of arsenic and iron is unlikely to underestimate health risks.

Vegetables

Vegetable samples were not collected in a systematic manner. As discussed previously, homes were sampled because the owners volunteered and only a small percentage of the homes had produce available for sampling. It is unknown how many homes in the Basin have vegetable gardens and whether the homes sampled were representative. Furthermore, the same produce was not sampled in every garden; the 24 sampled gardens did not have similar produce and a wide variety was sampled. Leafy vegetables and root vegetables were preferentially sampled from every garden, if available. For some types of produce only a few samples were collected and for some only one sample was collected. Because of the non-systematic sampling and the small data set, the vegetable data are considered semi-quantitative. It is unknown whether the data underestimated or overestimated the metal concentrations in homegrown produce. The estimated HQ associated with cadmium in vegetables is 2, which exceeds the target health goal of 1. Issues surrounding cadmium in vegetables are discussed further in the following text.

The database for cadmium concentrations in garden soil is much larger than that for cadmium in vegetables. When the concentrations of cadmium in vegetables are compared with the cadmium concentrations in collected garden soil, no trends are apparent. Figures 7-1 through 7-3 show scatter plots of cadmium concentrations in vegetables and soil for (1) all vegetables, 31 paired samples; (2) leafy vegetables, 11 paired samples; and (3) root vegetables, 19 paired samples. The plots do not indicate a relationship between cadmium concentrations in vegetables and soil (i.e., vegetable concentrations do not increase as soil concentrations increase). As a result, it is not possible to use cadmium concentrations in garden soil to determine whether the homes sampled for homegrown vegetables were representative of the entire site. The average concentration of cadmium in leafy vegetables is 0.42 mg/kg and in root vegetables it is 0.13 mg/kg. These concentrations are higher than those indicated by national survey data, which show the mean cadmium concentration in leafy vegetables as 0.033 mg/kg (ranging from of 0.016 to 0.142 mg/kg) and in root vegetables as 0.016 mg/kg (ranging from a trace to 0.028 mg/kg) (Gartrell et al. 1986). The average cadmium concentration in root vegetables in the Basin is higher than the highest value reported in ATSDR (1993). Recent surveys by the Food and Drug Administration (FDA) note that 80 percent of cadmium in the diet comes from lettuce, potatoes, and grains (Gunderson 1995).

Garden vegetables and garden soil were sampled at homes in the BHSS (PHD et al. 1986) in 1983. The dry-weight results for cadmium concentrations are compared with EPA's 1998 sampling results for the Coeur d'Alene Basin in Table 7-2. The sampling results are provided in Appendix B. Only dry-weight values were reported in the 1983 data; therefore, EPA dry weights are used for comparison. Exposure to vegetables occurs to the wet product; therefore, wet-weight concentrations were used in the hazard calculations and wet-weight concentrations are shown in the figures. Wet-weight concentrations are much lower than dry-weight concentrations because vegetables contain a large percentage of water.

The 1983 and 1998 vegetable data are similar. Both indicate that leafy vegetables have higher concentrations of cadmium than root vegetables and that concentrations are a similar order of magnitude.

In conclusion, leafy vegetables, particularly lettuce, in the Coeur d'Alene Basin appear to have the highest concentrations of cadmium. This finding agrees with national survey information indicating that this vegetable type generally has the highest cadmium levels. (The latest FDA survey indicated that potatoes contain slightly higher cadmium concentrations than leafy vegetables [Gartrell et al. 1986]). Average cadmium concentrations in leafy vegetables and root vegetables in the limited data set for the Basin available appear to be higher by almost an order of magnitude than the national averages, and Basin concentrations are similar to those found in Pinehurst in 1983 (PHD et al. 1986). Cadmium concentrations in vegetables in the Basin do seem elevated compared to the rest of the country.

Health risks due to cadmium in vegetables were estimated using a total vegetable ingestion rate for homegrown vegetables that was not vegetable specific. Actual health risks could be higher or lower, depending on the amount of leafy vegetables versus other types of vegetables consumed. On average, cadmium concentrations in leafy vegetables were three times the concentrations in root vegetables. Hazards due to cadmium in vegetables exceeded the target hazard goal, indicating that this may be an exposure pathway of some concern and potentially worth evaluating further to eliminate some of the uncertainty.

7.3.2 Exposure Assessment

Gastrointestinal Absorption of Arsenic From Soil

As recommended in EPA Region 10 guidance, a gastrointestinal absorption factor of 60 percent was used in exposure estimates for arsenic ingested in soil (USEPA 2000b). Confidence in the data set used to estimate 60% absorption is limited. Actual bioavailability is likely to vary across the site and would be higher or lower than 60%. In portions of the Basin, arsenic derived from residual smelter emissions may be more bioavailable than 60%. The EPA oral RfD and SF for arsenic were derived on the basis of an epidemiological study of a group of people who were exposed to high levels (e.g., intake of approximately 1,000 µg/day) of soluble arsenic in food and water. However, arsenic ingested in soil at mining sites is generally less well absorbed than soluble arsenic in food and water because (1) the arsenic form may be relatively insoluble (Davis et al. 1996), and (2) arsenic adsorbs to soil particles, making it less available for absorption (Valberg et al. 1997). Therefore, the gastrointestinal absorption factor of 60 percent was used to account for differences between the bioavailability of arsenic ingested in soil at the site and the bioavailability of soluble arsenic ingested in water and the diet in the study used to derive the SF.

EPA Region 8 has used a generic gastrointestinal absorption factor for arsenic in soil of 80 percent for arsenic in smelter-derived waste and 50 percent for arsenic in mining-derived waste (USEPA 1993a). The assumption of lower bioavailability of arsenic in soil has been tentatively confirmed by results from animal studies indicating that soil-bound arsenic is not as bioavailable (8 to 48 percent) as arsenic in solution (Freeman et al. 1993, 1995; Groen et al. 1994; Yanez et al. 1993). However, the number of animals used in the study was small. In addition, a number of human studies have reported low urinary arsenic levels at sites with high arsenic concentrations in the soil, probably as a result of the low bioavailability of arsenic in soil (Butte-Silver Bow Dept. of Public Health and Cincinnati Dept. of Environmental Health 1992; Colorado Dept. of Health et al. 1990; Hewitt et al. 1995; Valberg et al. 1997). Site-specific gastrointestinal absorption factors for arsenic have been derived using soil from the Murray Smelter Superfund site in Utah (24 percent), and residential soil (80 percent) and slag dust (42 percent) from the Ruston/North Tacoma Superfund site in Washington (Weis, Henningsen, and Griffin 1996; USEPA 1993b, 1996d, 1997d).

The gastrointestinal absorption factor of 60 percent used in this risk assessment is within the range of values discussed. However, this is a source of uncertainty in the estimates of hazard/risk due to arsenic ingestion in soil.

Current Conditions Do Not Change

EPA residential exposure assumes that the current conditions remain the same over 30 years of exposure. Over this period, conditions may improve (e.g., many areas will be cleaned up after which cleaner sediments potentially will be deposited over the formerly contaminated areas) or, conversely, areas now contained could be disturbed (e.g., large flood events mobilizing new waste pile materials with high concentrations of metals). Any of these conditions could affect the actual amount of exposure.

7.3.3 Toxicity Assessment

Arsenic Toxicity Issues

There is uncertainty associated with the effects of arsenic at low exposure doses. Because of the controversy surrounding the carcinogenicity and toxicity of ingested arsenic, further revisions to the SF may occur in the future. Some of the outstanding issues include (1) a possible threshold dose (i.e., risks are less than predicted based on the linear model relationship between dose and cancer risk at low doses); and (2) the possibility of internal cancers induced by ingested arsenic, particularly of the bladder and lung. On balance, the SF could be underestimating or overestimating risk.

The risks presented here for arsenic were calculated based on the total arsenic concentrations in each area. However, some of the arsenic is naturally present (pre-mining background concentration). For example, the 90th percentile soil background concentration for arsenic is estimated to be 22 mg/kg (Gott and Cathrall 1980). This concentration is based on un-sieved soil samples rather than sieved soil samples used in the EPA risk equations; comparable sieved background levels would be expected to increase. Of the 26 different arsenic EPCs for soil and sediment used in the RME risk and hazard calculations, only 4 were less than or equal to 22 mg/kg (Table 3-2). The arsenic concentrations used in the risk and hazard calculations are not 90th percentile values, but 95 percent upper confidence limits of the mean (UCL_{95}). The background UCL_{95} for arsenic is unknown and cannot be estimated from the Gott and Cathrall report where only the 75th and 90th percentile values for arsenic were provided. The 75th percentile concentration was 10 mg/kg and a background UCL_{95} for arsenic is thus potentially lower than 10 mg/kg. Therefore, all the arsenic soil EPCs are potentially greater than a UCL_{95} natural background value.

However, for many of the soil and sediment EPCs close to 22 mg/kg, background may be contributing significantly to the total arsenic concentration. Risk management activities typically take background concentrations into account for decisions about remediation. Thus, background may account for a large percentage of arsenic risks in some areas and may affect remedial decisions. When considering the contribution of background to risks, the bioavailability of arsenic in background soil as compared to arsenic in mining-impacted soil must be taken into consideration as well as the total background concentration. Another area of uncertainty is that background arsenic may have a different bioavailability than arsenic in mine wastes and thus risks would not be equal given equal soil concentrations. If bioavailability was equal, at an arsenic concentration of 10 mg/kg, risks for residential exposures would be 3×10^{-5} (ingestion and dermal soil exposure, 60 percent gastrointestinal absorption rate). Cancer risks from arsenic due to residential soil exposure (highest risks) ranged from 5×10^{-5} to 1×10^{-4} for the eight residential areas evaluated (current conditions). Therefore, where risks from residential soil exposure are at the low end of the calculated risk range, below 6×10^{-5} (Kingston, Silverton, and Wallace), risks from a natural background concentration of 10 mg/kg could account for half the risk. For the five remaining residential areas which had risks from residential soil of 1×10^{-4} (Lower Basin, Side Gulches, Osburn, Mullan, and Nine Mile), the risk due to the background concentration of arsenic could account for approximately 30 percent of the risk. The incremental increases in risk above background are approximately 3×10^{-5} and 7×10^{-5} for the lower risk and higher risk areas, respectively. All increases above background are, therefore, greater than 10^{-6}, even if bioavailability is assumed to be the same and the background UCL_{95} is assumed to be 10 mg/kg. This same discussion would also apply to noncancer hazards due to arsenic.

Reference Dose for Iron

The RfD for iron is a provisional one; it has not gone through the peer review process necessary for its inclusion in the EPA on-line IRIS database. Therefore, the provisional RfD may be reevaluated and subsequently be raised or lowered. Such a change would increase or decrease the hazard estimates for iron in this report.

COPC Interactions

The potential toxicity-modifying interactions between COPCs in the Coeur d'Alene Basin are numerous and complex. Some of these interactions could be expected to increase toxic effects, some would reduce toxic effects. The following examples illustrate some of the complexities and potential interactions (TVA 1999):

- Several of the COPCs are required for nutritional adequacy (iron, manganese, and zinc) and have limited toxicity unless intake is excessive or through an inappropriate pathway. For example, an iron intake of 0.3 mg/kg body weight is recommended for nutritional adequacy, and an oral dose in excess of 40 mg/kg body weight is likely to be toxic. The RfD used in the hazard calculations for iron was 0.3 mg/kg and hazards slightly greater than 1 are, therefore, unlikely to be a health concern for a child who has an adequate nutrient intake.

- Some COPCs that are essential nutrients may have adverse effects by altering the physiological balance with another essential nutrient COPC. For example, iron deficiency increases the absorption of ingested manganese.

- The toxicity mechanisms of some of the COPCs are at least partially attributable to interference with normal metabolism of the COPCs that are essential nutrients. In some cases, toxicity may be ameliorated by providing what under normal circumstances might be considered an inordinate level of an essential nutrient. For example, cadmium may cause anemia by interfering with normal iron metabolism and absorption. These symptoms can often be alleviated by zinc supplementation.

- Dietary status may influence an individual's response to some COPCs. For example, calcium deficiency and/or physiological states causing remobilization of calcium stores (e.g., pregnancy, lactation, and aging) may increase both the absorption of ingested lead and the concentration of lead in critical organs. Iron deficiency and/or physiological states associated with increased iron requirements (e.g., infancy) enhance lead absorption and promote lead toxicity. An inadequate dietary intake of protein, methionine, or choline may limit the ability of the liver to methylate arsenic, thereby limiting arsenic detoxification and excretion.

Interactions between COPCs may result in synergism or antagonism related to the toxic effect of individual COPCs and may even fundamentally alter the mechanism of the toxic effect in vivo. For example, rats exposed to mining waste that was contaminated primarily with arsenic, manganese, zinc, copper, and lead showed an apparent interaction between arsenic and manganese. The interaction appears to influence the bioaccumulation of arsenic and manganese in brain tissue and alters the release of the neurotransmitter dopamine in areas of the brain involved in motor activity, attention, and learning (Rodriguez et al. 1998).

Humans (as well as most other animals) produce intracellular proteins called metallothioneins that reduce the toxicity of metals, possibly by sequestering reactive metal ions in the cytoplasm away from critical organelles such as the nucleus and mitochondria. Metallothioneins are produced at some baseline level in all tissues under normal conditions, but they can also be “induced” by exposure to several metals, including zinc, cadmium, copper and manganese (i.e., the exposed cells increase their synthesis of metallothioneins). By this adaptive physiological mechanism, previous exposure to sub-lethal levels of toxic metals “boosts” tolerance to subsequent exposure, thus shifting the dose-response curve to the right (Klassen and Liu 1998). Theoretically, exposed resident populations with low-level chronic exposure to metals at the site might be less susceptible to the toxic effects of those metals.

The potential effects of exposure to several of the COPCs, especially those classified as essential nutrients, may also be modulated by homeostatic mechanisms, including the following:

- Limitation or enhancement of uptake from the gastrointestinal tract (e.g., iron)

- Alteration of the rate of excretion (e.g., manganese).

The magnitude of the effect of these homeostatic mechanisms would be expected to vary, depending on factors such as age and nutritional status (TVA 1999).

7.3.4 Risk Calculations

The effect of combining uncertainties associated with the various assumptions in the risk assessment is partially demonstrated by the difference between “typical” (average) and RME risk calculations. To address potential uncertainties, a number of conservative estimates were used for the RME calculations, which when combined could overestimate risk considerably for most individuals. As noted by Habicht (1992), maximizing all variables will result in an estimate that is above the actual values seen in the population in virtually all cases. This recent guidance, therefore, recommends (1) the use of near maximum values for one or a few variables with the majority being mean values, and (2) the evaluation of an average case for comparison.

7.4 UNCERTAINTIES IN LEAD RISK ASSESSMENT

Each of the parameters and assumptions made in the lead health risk analysis have some associated degree of uncertainty. The data utilized in developing quantitative estimates of risk variables and parameters, and the likelihood of the assumptions made regarding each parameter, should be considered in assessing the results of the risk calculations. Most of the data collected to represent exposure and response variables and to support the development of exposure factors, were collected by standard methodologies employed in the area for many years. These methods have been peer-reviewed and critiqued by various agencies prior to implementation. For many of the parameters, typical values have evolved from other studies and guidance and have been broadly applied in similar risk assessments. Other parameters are more site-specific in nature and subject to greater range of uncertainty. Additionally, the data used were a compendium of results from a number of studies that were designed and carried out for different objectives. As a result, some uncertainty is introduced from the combining of these studies.

There are five areas of uncertainty in the overall human health risk characterization for lead that are discussed in this section: i) observed blood lead concentrations and distributions in the various populations at increased risk for lead, ii) environmental data collection and evaluation including sampling and analysis protocols, iii) the broad range of exposure parameters linked to characterizing both baseline and incremental lead exposures, iv) the multiple areas of uncertainty and variability in the modeling of blood lead levels, and v) uncertainties associated with modeling results employed to derive risk-based soil lead cleanup levels.

7.4.1 Uncertainty in the Use of Observed Blood Lead Levels

Uncertainty in Blood Lead Measurements

All blood lead samples for both the Basin and the BHSS are venous samples drawn by a certified phlebotomist. Basin samples were drawn at fixed site screenings utilizing school buildings, and BHSS samples were drawn in a hospital setting. All samples have been analyzed at the same CDC certified laboratory for the last 15 years and are subject to all Public Health Service protocols and QA/QC procedures. More than 5000 blood lead samples have been collected and analyzed in the Silver Valley by this procedure. Risk managers should consider the measured blood lead levels to be reasonably accurate.

Uncertainty in Representativeness of Blood Lead Surveys

The blood lead surveys conducted by the State and local health departments were estimated to have sampled about 25% of the 9-month to 9-year old children living in the eight geographic Basin subareas. These data were used in the HHRA i) to characterize excess absorption levels among different age groups in the various geographic subareas, ii) as a dependent variable in quantitatively assessing dose-response relationships with independent environmental source variables, and iii) to compare to blood lead modeling estimates to assess the effectiveness of different model forms in describing current blood lead levels.

Review of these data indicate significant excess absorption is occurring, particularly among younger children, in several areas of the Basin. A strong quantitative relationship (R-square = 0.60, p=0.0001) between blood lead levels and soil, dust and paint lead concentrations was noted. This empirical relationship was subsequently used to predict the effect of exposure reductions on future environmental and blood lead levels. A site-specific form of the IEUBK Model for lead, the “Box Model” used for the BHSS provided reasonably accurate predictions of observed blood lead levels and percent to exceed toxicity criteria for areas east of the BHSS. The EPA Default Model tended to over-predict current blood lead levels in these areas. Both models under-predicted observed blood lead levels in the Lower Basin.

Each of these findings is based on an inherent assumption that those individuals providing blood samples are representative of the overall population of the Basin. This may or may not be the case. The sampled population was self-identified in response to solicitations from the health departments over a period of four years. In 1996, the area was systematically canvassed and a randomized sampling of 843 homes across the Basin was obtained. Although the participation rate for environmental sampling of these homes was adequate, few parents availed themselves of the opportunity to have their children tested. More than 660 adults agreed to provide blood samples. However, only 98 children were tested in the 1996 survey.

The latter three screenings were voluntary and directed more toward health intervention efforts and showed different participation rates. Children from age 1-9 years were tested, although tighter age band sub-grouping results were presented. In 1999, extra solicitation efforts were applied including additional publicity, public and monetary support from the local mining industry, and a $40 per child financial incentive. This survey resulted in a turnout estimated near 25% of the eligible children in the Basin and a doubling of the total blood lead observations obtained. The overall response over the four years was biased toward older children, with about twice as many children in the 7-9 year category than 9-month to 36-month old children. The nature of this turnout raises questions regarding the reliability of using these data in the HHRA and subsequent remedial decision-making. The implications of the uncertainty in the representativeness of the observed blood lead database are discussed below for each major use of information.

Characterizing Excess Absorption in the Population. Review of the blood lead data indicate that about 10% of the 9-month to 9-year old children tested are experiencing excessive blood lead levels. The high blood lead levels are concentrated in younger children with 23% of 9-month to 36-month old children showing levels of 10 μg/dl or greater and 10% at 15 μg/dl or higher. A significant portion of these children (3%) are in the medical response category greater than 20 μg/dl. These results indicate an unacceptable level of absorption is ongoing among, at least, the younger children participating in the intervention program.

Blood lead screening has associated problems that can result in uncertainty and variability, as noted in Table 7-3. Much of the variability and uncertainty is related to the relative instability of this measure in young children. Blood lead levels may change with increases or decreases in lead intake. Questions leading to uncertainty in results include the extent to which those screenings with low turnout would be representative of those individuals, especially children, who did not participate.

One statistical problem noted in screenings of this type is participant selection bias. Two potential biases are important to consider. The announcement and implementation of the surveys and associated education efforts may have caused parents to undertake exposure reduction efforts with their children that result in lower blood lead levels. These same children may have been more likely to participate than those from uninformed families. The nature of the solicitation may have resulted in drawing from particular segments of the population that exhibit higher or lower blood lead levels.

It is not clear the extent to which the publicity and concerns raised about scheduled screenings would have affected blood lead in response to any abrupt lead exposure changes elicited by care giver concerns (Mushak 1998). Judging from the low participation rate in earlier screenings, there seems to be a differential attitude within the Basin as to the seriousness of the lead exposure problem. Many community members feel strongly that there are few health risks ongoing and resent the government intervention and investigation efforts. These factors could affect the relative seriousness of care-givers attempts to prevent exposure for their children among those who elect to participate. That is, those parents most concerned will willingly use the opportunity of a community screening to have their children tested. But they may also be those who extend their concerns about lead hazards to daily exposure prevention activities for their children as well. That is, those most likely to participate are those whose children represent a likely lower level of exposure than those care-givers who are indifferent to both needs for blood lead testing and children's activities in a lead-contaminated environment (Mushak 1998). This would suggest that blood lead levels among the non-participants would be expected to be greater than those that provided samples.

On the other hand, the use of money as an incentive would be expected to particularly favor low-income participation. Because potentially high exposures are associated with poverty-related factors, higher than average blood lead concentrations would be expected among the participants. More than 30% of young children in the Basin are classified a being in poverty and a majority of families with young children could possibly be considered low-income. As a result, it is unclear whether the observed blood lead levels noted in the health department surveys are higher or lower than those children not tested.

This question was examined in the BHSS where a door-to-door screening has been ongoing for over a decade. In the BHSS, recent turnout has been about 50% of the population down from more than 70% in the early years of the program. Of those that don't participate, about 6% are not found in door-to-door solicitations despite repeated efforts, 4% indicate previous testing, 10% believe there is no problem, 8% give no reason, and samples are unobtainable from 10% (TerraGraphics 2000a). The only particular bias identifiable among non-participants was among those that were tested before with negative results. These families would be expected to have low blood lead levels. Coupled with the monetary incentive that favors low-income participation, this factor would suggest that overall blood lead levels at the BHSS would show lower incidence of exceedance than observed among participants. No such information exists for the Basin population.

Comparison to Health Criteria and Other Populations. There are problems in comparing Basin blood lead levels to State and national surveys. The Basin-wide 1999 blood testing results of 10% exceeding the level of concern, cannot be directly compared with a State-wide survey conducted in 1997 that found that 4.2% of pre-school children living in pre-1970 housing had blood leads greater than the level of concern because i) all the children in the Basin do not live in pre-1970 housing, ii) children 9 months to 9 years of age cannot be compared to a population of pre-school age children, and iii) the 10% exceedance in the Basin may be the result of a bias in sampling of older children, and the influence of education and intervention activities; the second of these at least would clearly not have been present in the State-wide survey.

These problems can be somewhat mitigated by examining only pre-school results in the Basin. Sixteen percent of preschoolers showed blood lead levels greater than or equal to 10 µg/dl in the most recent survey. Housing data for the Basin indicate that about 48% of housing in the Basin has been built since 1960 compared to 37% statewide, although the housing age breakdown for the children providing blood lead samples is unknown. This question is also compounded by the age distribution of children in the Basin and the subset of the population providing samples. There has been a preferential loss of younger children in the population in the last decade. The percent of children under 5 years of age has decreased by 12% as compared to an 8% decrease for all children under age 18 in the last decade. The degree to which this difference affects population blood statistics or the demographic characteristics of the preschool children remaining in the valley is unknown. With regard to risk assessment considerations, future populations would see a repopulating of the lower age groups as economic conditions improve. These families would likely be new to the area, less acquainted with lead health risks, and less affected by intervention efforts. As a result, it is likely that the prevalence of excess absorption is substantially higher in the Basin than the in Idaho generally. Risk managers may want to consider that those newcomers to the area in the future may have higher dose response rates than the current population.

Comparisons of Basin blood lead levels to national statistics is also problematic as there is clear stratification in national blood lead levels with children's age, income, age of housing, ethnicity, and size of community. These factors interplay in complex ways. Living in older poorly maintained housing may introduce additional sources of lead. However, low income status may not be a direct cause of elevated blood lead levels, but rather reflect such co-factors as poor nutritional status and having to live in older homes because they are generally less expensive and the resulting higher exposures from greater dust and lead loading rates in older homes. Both a reduced nutritional status and increased dust exposures in older homes are arguments for greater risk reduction efforts.

It is not readily obvious how the Basin should be characterized relative to the national demographic considerations. The area is not ethnically diverse and observed blood lead levels were drawn from the largely white resident population. The Coeur d'Alene Tribe, for the greatest part, resides outside of the area of contamination. No blood lead observations specific to Tribal members are available. Community size is small to rural and currently has a high incidence of poverty among young families. However, much of the poverty and low income status has been incurred in the last two decades associated with economic downturns in the mining industry. As a result, previously established community infrastructure, local government services, a stable older generation, and a tradition of community self-reliance in place prior to the economic downturn have helped to mitigate risk co-factors associated with poverty and comparison to other low income areas may not be justified.

Calibrating or Validating Predictive Models. It is important to note that neither the EPA Default or the Box Model were calibrated to observed blood lead levels in the Basin. The EPA Model was validated using blood lead levels from a variety of sites nationally and the parameter values are expected to provide representative estimates of blood lead levels based on health protective assumptions. The Box Model was developed through structural equation analysis of the last twelve years of blood lead and environmental exposure data collected through the course the BHSS cleanup. Both models were run "as is" and results were compared to observed levels in the Basin. No adjustment specific to observed Basin blood lead levels was made.

In comparing projected lead absorption results to observed blood lead levels, there is concern that observed values may not represent true baseline blood lead levels in the Basin. Blood lead levels may be biased high or low by selection factors discussed above. Additionally, observed levels may actually be reduced due to several factors, including the influence of a general community awareness of the lead problem, and as a result of general health education and specific intervention activities in the Basin. Analysis of the Lead Health Intervention Program developed for the BHSS indicate that community education and intervention activities have a substantial effect on reduction of blood lead levels in children. It is unclear how much the introduction of LHIP activities in the Basin in 1996, or the media and public attention to the potential problems have affected people's behavior with respect to lead exposures. However, any effect these efforts had likely resulted in lowering blood lead levels and particularly among those that provided samples. Many of the children whose families received follow-up counseling provided samples showing lowered lead levels in subsequent years. Siblings in these families and possibly acquaintances and neighbors would have similarly benefitted. As a result, risk managers might want to consider that model predictions based on default assumptions are likely to over-predict this population under current conditions.

Two general types of blood lead modeling were performed in the HHRA. These two methods are generally called conventional (e.g., a predictive, mechanistic approach to blood modeling) and site-specific analysis (e.g. a descriptive, empirical approach). The traditional IEUBK approach is intended to be predictive of future, potential blood lead levels associated with a site. The site-specific approach more accurately describes past blood lead trends and current conditions; its predictive value for future blood leads may be contingent upon sustained efforts and efficacy of the Lead Health Intervention Programs to monitor blood lead levels and reduce exposure in perpetuity. This possibility, in addition to the self-selection bias toward children in the older age groups may result a significant reduction of observed exceedances of 10 µg/dl blood lead.

As a result, Box Model developed for the BHSS may inherently reflect some suppression of the dose-response relationship between blood lead levels and environmental exposures. Those same factors may be present in the Basin and partially account for the quantitative site-specific and the Box model's performance in describing observed concentrations and percent to exceed critical toxicity levels. There is a possibility that the relationships described in the site-specific quantitative models and the IEUBK Box Model may not apply to future generations and environmental conditions in the Basin. On the other hand, future improvement in the economic situation could mitigate those dose-response factors associated with poverty and the overall dose-response rate for the community could improve. However, particular families that remain poor would continue to be at increased risk. To err on the side of protectiveness, risk managers may want to consider the Box Model as a minimum expression of the dose-response relationship.

Screening for High Blood Lead Levels Intervention Activities. Turnout for the Basin-wide intervention program has been disappointingly low, although not atypical for fixed-site screenings. The primary purpose of the intervention screening is to identify children with high blood lead levels and to provide follow-up services that can help to reduce exposure and consequently, excess absorption. Review of the population statistics suggests that only one-in-four 9 month to 9 year old children is being sampled. The participating population is skewed toward 7-9 year old children, resulting in a substantially lower participation rate among 9-month to 36-month old children. Among the young children (9-month to 36-month olds) participating, 22% have blood lead levels exceeding 10 µg/dl and 10% exceed the 15 µg/dl criteria. As a result, it is likely that the majority of children experiencing excessive blood lead levels are unidentified and receiving only the general education benefits associated with the intervention program and no individualized health response. This finding suggests that increased surveillance and more aggressive intervention efforts may be required in the interim until permanent risk reduction actions can be put in place, and that the efficacy of long-term intervention as a health protective measure is in question.

7.4.2 Uncertainty in Data Collection and Evaluation

Qualitative statements of uncertainty for environmental data gathering within various segments of the Basin for lead and non-lead contaminants include sampling procedures and post-sampling measurement methodologies. The uncertainties associated with blood lead data gathering are summarized in Table 7-3. Three basic questions are addressed with respect to variability and uncertainty with the use of these data in the HHRA:

> --Do lead and the non-lead contaminants potentially occur in various environmental media present in areas of the Basin at sufficient concentrations to produce levels of concern for health?
>
> --Are the levels of lead and non-lead contaminants in site media different from background levels? That is, are levels of these substances higher than would be the case in the absence of historical mining, milling and smelting activities?
>
> --Were the sampling plans, in terms of both numbers and types of sampling, adequate to characterize lead and non-lead contaminants in each exposure source and pathway?

Table 7-4 summarizes the elements of uncertainty associated with data gathering and evaluation with reference to environmental sampling and analysis for lead. The Table includes likely direction of bias to the media-specific lead measurements. Comparatively speaking, the level of uncertainty in media sampling for lead concentration or lead loading is arguably less overall than that residing in the parameters associated with lead exposures (exposure factors) and lead risks (measured and/or modeled blood lead levels).

An underlying assumption with environmental lead data collection, an assumption with its own uncertainty, is that the types of environmental media sampled adequately reflect all the media that would be encountered by human populations. This is especially of concern later in the process, during risk characterization, where all media at issue would or would not be entered into the applicable model.

A wealth of data exists to identify what would most certainly be those lead sources and pathways most relevant for the Basin. Expert consensus documents exist to identify and validate these for application to almost all human populations (NAS/NRC 1993; CDC 1991; ATSDR 1988, 1992, 1999b; USEPA 1986). Similarly, considerable data exists to specify likely environmental lead inputs to either ad-hoc, statistical models in the form of multi-regression models or mechanistic models such as EPA's Integrated Exposure-Uptake Biokinetic (IEUBK) and Adult Lead (ALM) models (USEPA 1994 a,b; USEPA 1996c).

Less obvious sources of environmental lead that may result in measurable intakes and some associated body lead burden may sometimes be difficult to identify and in theory add an element of uncertainty about all lead sources. In the case of the Basin, it is unlikely that such idiosyncratic lead sources comprise any significant increment of exposure. Of particular concern would be ethnic dietary components and folk medicines that are known to add sizeable amounts of lead to human intake. For example, imported canned foods may still have lead-seamed cans, while some preparations for traditional home treatments for pediatric ailments can contain high lead levels. The Basin population, however, is relatively homogenous demographically, such that few idiosyncratic sources of this type are likely significant.

General Soil and Sediment Sampling Plans

The risk assessment for both lead and non-lead contaminants incorporated only a portion of the many thousands of soil and sediment samples that have been collected throughout the Coeur d'Alene River Basin over the past 25 years. Two criteria for incorporation were that the soil samples had been sieved to a uniform fraction of particle sizes and sizes more reflective of likely human contact, and the samples had to have been collected from sites along and within the Basin where some human contact would occur. This is not to say that exposures of and toxicity to ecological systems and populations would not occur where human contact is unlikely at present or in the future.

A matter of more concern in the above connection is the extent to which current or likely future human contact patterns are adequately addressed within the human residential or recreational areas addressed in this HHRA. This uncertainty cannot be totally resolved as projecting future land use practices involves a complex mix of economic and demographic/sociological factors.

Sampling for Yard Soil Lead in the Basin

Soil lead data available under the above criteria were gathered from the 1996 ATSDR/IDHW survey, two selective repeat screenings in 1999 and various EPA field samplings (notably the FSPA06, -07, and -12 samplings). Nearly half of the homes in the Basin were sampled for lead in soil in the course of the above efforts, amounting to about 1020 homes within both the 1996 and 1999 screenings by the State of Idaho and the FSPA06, -07, and -12 efforts.

How much uncertainty is associated with the merging of the various lead data sets from IDHW's 1996 and 1999 efforts and the EPA samplings? Any answer to that question is tempered by a trade off between the statistical and interpretive advantages gained for the Basin risk assessment through sizeable increases in the sample size through data merger, i.e., reduced uncertainty, versus the consequences of differences encountered in having different soil sampling protocols, ATSDR/IDHW vs. EPA, and differences in recruitment protocols.

Recruitment differed between the 1996 and the later EPA protocols, and some uncertainty as to the consequence of this for soil contaminant assessment exists. For lead and non-lead contaminants, homes in the Basin were self-identified through a voluntary call-in basis in the EPA screenings. For lead and cadmium, the IDHW/ATSDR homes were selected randomly from within the entire population of homes in the Basin. This began with a census of the study area for participants and non-participants. Data collection was preceded by public meetings and availability sessions about three weeks before actual sampling began. Household and individual questionnaires were used for participants.

Sampling protocols of yard soils differed between the State and EPA screenings. Neither technique conducted preliminary discrete core analyses to determine the in-yard variability of soil lead concentration. Because soil lead levels within a yard are likely log normally distributed, the more aliquots that are collected in composite sampling, the higher the probability of including a hot spot, and there are likely more typical aliquots to dilute the hot spot contribution. As a result, the more aliquots collected, the better the representation of true media concentration. It is typically the case that selected compositing protocols await the outcomes of a screening analysis using discrete samples. Both surveys relied on techniques developed at other sites to determine the compositing rate for yard soils.

The IDHW/ATSDR study collected a single composited core sample from a minimum of two and a maximum of 10 cores per yard per 500 square feet, as being representative spatially of the likelihood of exposure population interactions with yard soils. This technique evolved from comprehensive studies conducted over a number years at the BHSS that has been successfully used to assess both dose-response relationships and characterize yards for remedial purposes.

The EPA surveys relied on techniques used at other mining sites in the western U.S. and sub-composited a number of subareas in each yard but did not collect all samples within sectors as discrete samples for analysis to permit assessment of contaminant level heterogeneity or distributions of contaminants spatially. Because the EPA's approach usually involved more aliquots, it had a higher probability of including a "hot spot" contribution. On balance, some uncertainty persists as to the representativeness of either protocol for a "true" sampling, and additional uncertainty exists as to the potential of the two different protocols to differentially depict an adequate expression of soil lead levels and their distributions within the Basin. This descriptor is uncertain as to how well it captures the full distribution of soil lead values in the Basin.

Analysis of twenty-three yards sampled independently, colleted by both methodologies shown in Appendix N, indicates little significant difference in overall lead levels, and none in cadmium concentrations. The difference noted in lead levels is associated with yards with extremely high concentrations that clearly represent excess risk by any analysis. With regard to the use of these data, both the predictive and empirical analysis relate the results, as obtained, to observed blood lead levels. Both models show a strong relationship that is effective in describing observed levels in those areas where residential soils are the largest contributor to exposure. It is likely, overall, that soil lead level data as merged for this risk assessment adequately represents typical or mean concentrations as used in subsequent analysis. However, these results may underestimate “hot spot” contributions, that may be significant in individual risk evaluations.

There is also uncertainty associated with soil sample preparation, specifically the sieve size used to segregate soil by particle size prior to laboratory analysis. All soil samples collected for health assessment or response actions in the Silver Valley for the last twenty-five years have been sieved to 175 micron particle size. Subsequent studies have shown that this size fraction is a reasonable expression of those particles that adhere to children's hands and are most active in the hand-to-mouth pathway of soil and dust ingestion.

According to the Technical Review Workgroup (TRW) for Lead Guidance Document from Short Sheet (EPA 2000c):

> Several studies indicate that the particle size fraction of soil and dust that sticks to hands is the fine fraction, and that reasonable high-end for this size fraction is 250 microns (μm) (Kissel et al. 1996; Sheppard and Evenden 1994; Driver et al. 1989; Duggan and Inskip 1985; Que Hee et al. Duggan 1983). This is also the particle size fraction that is most likely to accumulate in the indoor environment, as a result of deposition of wind-blown soil and transport of soil on clothes, shoes, pets, toys, and other objects. Lead concentration data for the fine (250 μm) fraction (Midvale data) were used in the calibration of the EPA Integrated Exposure Uptake Biokinetic (IEUBK Model for Lead in Children, and in the characterization of lead bioavailability in soil, using either *in vivo* or *in vitro* studies (Casteel et al. 1997; Maddaloni et al. 1998; Ruby et al. 1996)

Sampling of Other Soils for Lead

In contrast to yard soils, it is likely that lead in soils and sediments in various common use areas would somewhat overestimate the levels that would be relevant to human exposures. This arises from the highly conservative assumptions (most protective against health hazard) employed for these 49 public areas (Sample N=647).

Five waste piles (Sample N=27) were included in the "neighborhood" soil lead scenario. These waste piles have particularly high levels of lead and can often contain readily ingestible particles that also readily stick to hands. However, the likelihood of direct children's contact in most of these cases is quite low in the case of infants and toddlers, but increases with older, more mobile children. Therefore, sampling and measurements for lead likely overestimate direct contact, and the amount of overall lead contact infants and toddlers will encounter in the Basin. These may or may not overestimate exposures of older, mobile children roaming freely in and around waste piles. To the extent older children transfer into the home smaller, high lead particles on bikes, shoes, clothing, pets, and from waste piles for younger sibling exposures, an indirect added exposure of the siblings is an area of remaining uncertainty.

House Dust Lead

House dust lead characterized as lead concentration or lead loading per unit surface area is typically gathered by various methods, all of which depict different spatial segments of home surfaces and engender sampling uncertainty at several levels. Therefore, one level of uncertainty in this environmental parameter has to do with which type of dust sampling is employed and which approach more accurately expresses the lead content of interior dusts. A second area of uncertainty arises within each sampling method. Basin house dust samples were gathered as either vacuum bag collections (N=320) or by entry dust mats (N=500). The former provided lead as concentration, while the latter permitted quantification in terms of lead concentration or lead loading (mg Pb/cm^2/day).

Conventional vacuum cleaners collect a broad range of deposited dust particles. This range is further complicated by the state of repair and efficiency of the units and depicts a general but variable expression of interior dust lead level. Uncertainty has to do with how well the range of surfaces vacuumed coincide with the surfaces contacted by children, especially infants and toddlers exploring their interior home environment. Dust particles largely adhere to children's hands, in contrast to soils where only the smaller fraction of soils are likely to do so. It is likely that some homemakers will vacuum thoroughly, including surfaces not encountered by children. Others would confine vacuuming to the areas in more common usage and that are likely to become more visibly dusty. The former vacuuming pattern may overestimate dust lead concentration with reference to children, while the direction of bias to measurement of more confined areas is not clear.

It is difficult to assess how well the mat dust sampling in this Basin study reflect general deposition of exterior dusts and soils outside of the short collecting protocol of the Basin studies. To the extent that household practice would be to more frequently vacuum entry way mats or carpet than the running collection time of mat loadings in this study, then mat lead measures overestimate actual likely persisting entry mat levels or loadings. To the extent that entry mat surface is largely ignored in vacuuming, then the short collection time in the Basin protocol underestimates likely dust lead content.

Lead-Based Paint

Considerable uncertainty attends the testing of lead-painted surfaces, simply because there are few methods that truly sample the content of lead in paint that infants and toddlers are likely to contact. Compounding the problem for Basin studies is the use of multiple measures for lead paint and the merging of this with expressions of painted surface condition. It is a problem in sampling statistics that the more expressions of concentration or loading for content of a substance, the more likely the finding that the substance has a more robust association with exposure than do those using other media. This is more likely to find statistical artifacts, rather than a true association.

Numerous expressions for lead in paint were employed in lead risk assessment, and these included use of the maximum level in the entire unit and the median level. Collectively, inclusion of these measures would likely overstate the level of lead in paint that is an accurate depiction of what children will encounter.

Groundwater

Groundwater sampling (N=80) was done from 27 monitoring wells sited near Nine Mile and Canyon Creeks. This water is not currently used as public drinking water and would only be an issue for future scenarios in land use where access to such waters might be required. In the latter case, extensive treatment might be required, limiting the extent to which lead levels would reflect human exposure levels. Uncertainty here is only for future likelihood of public consumption.

Surface Water Sampling

Measurement of lead and other contaminants in surface waters entailed a procedure in which sediments were stirred for suspension into the water column and then lead measured for the suspension samples. This would of course have produced a significant overestimation of what lead level would reside in either the water column itself or water with moderate amounts of sediment under less disturbed, non-flooding conditions.

Garden Vegetables

Vegetable sampling for lead is riddled with uncertainties of various type:

--What crops are grown by residents in the Basin and should these be preferentially sampled for lead?

--What is the range of vegetables which could be grown in the Basin, whatever the popularity of current crops, and should all crops be sampled equally for lead?

--In the absence of measurement data, what bioconcentration factor, linking lead in soil to metals in plant, should be used for estimate of plant lead uptake?

--Should results for washed or unwashed samples be used, given that part of garden crop lead content is from incorporated lead and part from external foliar, root or fruit surface contamination?

-- Use of wet weight or dry weight concentrations?

Lead measurements in garden samples in the Basin were performed on all produce samples, along with testings of arsenic and cadmium. The sampling was opportunistic as described earlier. Available data for crop lead do not indicate whether actual lead samplings of garden produce would tend to bias the actual levels of lead relevant to human intakes upward or not. As examples, parameters affecting sampling results in terms of lead concentrations include garden size (how to sample areal segments), when during the growing season the samples were taken (net level of lead changes during growing season), rainfall during the growing season which affects growth rate, splash contamination of foliar and fruit surfaces with soil as well as frequency of dust wash-off from plant surfaces prior to testing. See also Section 7.3.

Fish

There a several insufficiencies in the fish tissue data. There is no accurate characterization of tissue levels available for the Coeur d'Alene Lake fishery, although this may be the source of most of the fish consumed in the area. Although the data collected for three species in the lateral lakes may represent that particular fishery, there is little information regarding fish consumption rates among either residents or the Coeur d'Alene Tribe. These data are for filleted fish that likely represent the favored preparation technique for sport fishery families, but may not apply to Native American subsistence populations. Perch from the lateral lake fish tissue study carry the highest lead load compared to other fish fillet species. Perch are a highly desirable and sought after food fish in this area, and it is not uncommon for subsistence fishermen to take "buckets" of perch home and these small fish may be preserved whole.

One disappointing aspect of the lateral lakes fish sampling effort was the relative lack of larger bullheads and perch in the samples. The majority of the sampled perch were of a small size that would likely be tossed back by many fishermen. Whether this size factor impacted the metal loads in the tissue is unknown, but it is important to note that perch are predatory on other smaller fish so a food chain bio-accumulation might be a consideration. Comprehensive sampling of fish populations, appropriate tissues, harvest and consumption rates by both Tribal and sport fishery families, and comparable background concentrations in areas unaffected by the mining industry will be required to appropriately characterize risks associated with fish in the CDAB.

Water Potatoes

This plant is reportedly dominant in the Tribal subsistence activities and is prepared in a number of ways that can significantly affect lead content. The water potato is more highly coated with sediment because of its habitat, and that this surficial sediment in the Lower Coeur d'Alene contamination can overwhelm the risk analysis. Depending on how fish and water potatoes were (and are) traditionally prepared and cooked (e.g., unpeeled and boiled, etc.) can increase total lead intake rates 50% to 80%. Use of the water potato as a surrogate for all floodplain vegetation consumed in subsistence activities likely overestimates total intake from these sources, as other foods likely have a lower adhered sediment content.

According to tribal representatives, it may be more likely that a current subsistence family would be eating fish fillets (rather than whole fish), but it is not likely that they would be peeling the water potatoes. This would continue to result in extremely high intake rates. There is data on background lead levels for water potatoes sampled from the St. Joe watershed wetlands at the extreme south end of Lake Coeur d'Alene (Campbell et al. 1999). These results for water potatoes in the St. Joe drainage show no detectable lead levels, compared to lead levels ranging from 0.33 to 127 mg/kg in the Lateral Lakes (wet weight detection limits of 0.04 - 1.8 mg/kg).

7.4.3 Uncertainty in Exposure Assessments

This section addresses lead intakes and associated uncertainties. Questions dealing with biokinetic issues (e.g., uptakes and dependence of uptakes on media lead content) are more appropriately noted in the next section, dealing with lead risk characterization. This division is consistent with EPA's preferred definition of exposure to mean media-specific intakes of lead. Elements of uncertainty for lead exposures in the Basin are summarized in Table 7-5. This portion of uncertainty analysis anticipates the use of exposure factors in either statistical (regression) or biokinetic models.

Intakes of lead are estimated at two rates. The central tendency (CT) intake measurement (for the main body of the population) is employed to derive baseline exposures and incremental exposures. The second uses a reasonable maximum exposure (RME) of intakes as the 95th percentile subset of the exposed populations. These individuals have increased, but not unlikely, incremental exposures compared to the bulk of individuals. CT and RME lead intake values are developed for upland parks, neighborhood stream sediments, public beach sediments, waste pile lead, and garden vegetable and fish consumption.

The principal areas of uncertainty in lead intakes that figure in predictive lead exposure model use for children and other risk populations include: ingested soil and dust, partitioning of intake into direct soil ingestion, and soil-generated dust, dietary lead intakes, inhalation of air lead or reentrained dust, ingestion of lead paint, dietary intakes, and incremental intakes of lead by (mainly) children in the Basin of garden vegetables, waste pile lead, neighborhood recreational and public use area lead intakes.

Uncertainty about intakes of media lead are compounded by the fact that there are demographically different populations: local residents and Coeur d'Alene tribal members. These groups stratify into demographically-defined risk groups based on the potential interactions with contaminated media. This HHRA distinguishes between these two populations through "subsistence" exposure scenarios that are largely theoretical. Neither traditional nor current "subsistence" exposures to lead are known to be occurring in this area. Establishing the total absence of any subsistence activity with concomitant high lead exposures may be problematic. In any case, the sections below address, where appropriate, tribal vs. non-tribal exposure scenarios.

Soil Lead Intakes

As noted in Chapter 3, soil is the principal medium that Basin dwellers of various demographic type, under various lead exposure scenarios, are likely to encounter. In common with most assessments of mineral industry impacts, the soil exposure pathway is complete for both tribal and local residents, and for children and adults. Soil is also a main source of lead in exterior and home interior dusts. Ingestion of soil is the principal route of exposure, although dusts can be inhaled after reentrainment or in occupational activities.

Numerous variables affect soil lead intake and each has associated uncertainty. These have been described in detail by Mushak (1998) and EPA's IEUBK model user's manual (1994). Some variables are generic and intrinsic, and some are Basin-specific. For example, the presence of Coeur d'Alene Tribe members with historically distinct practices within the lower Basin produces a set of soil lead exposure scenarios that differ markedly from the typical case for other residents. Other variables include age, the absence or presence of abnormal ingestion rates of soil (in children called pica), the fractional distribution of children's time and activities between interior and exterior settings, the relative interactions with residential soils versus soils in the neighborhood, at daycare centers, kindergartens, parks, common use areas, and in the case of the lower Basin, beach and waterfront park contacts.

Considerable uncertainty surrounds the various attempts to quantify soil lead intakes, especially for the young child. This document assumes that soil intakes for adults and older children differs markedly relative to young children. At the same time, as noted by Mushak (1998, 1991) there is a relatively wide distribution of soil ingestion rates across groups of children and within a given period of time for an individual child.

Various studies have reported different soil ingestion rates for the infant and toddler. These differ with respect to study design protocol, the selection of which chemical tracers, the time intervals of the study and confounding variables, such as attributing to soil some tracers that co-occur in diet and may overstate the daily soil intake. The data of Calabrese and Stanek (1995) and Stanek and Calabrese (1995) as analyzed by Mushak (1998) indicate that soil ingestion rates are probably more variable across time and children, and within a given child's activities, than previously assumed. Even in the case of the Calabrese testing series, this group's later studies have continually refined their earlier studies with changes in estimates being required. At this time, there are improved data regarding ingestion rates of soil for infants and toddlers but no rigidly defined values, due to the considerable variability that occurs.

The EPA has extensively reviewed the various studies and the associated variability and uncertainty in observed ingestion rates. Overall, the current default selections for age-variable soil intakes for the most vulnerable subsets of children in the total age band 0-84 months in the IEUBK model, a range approximating 85 to 135 mg/day, are reasonable depictions of mean levels. For any adult lead exposure modeling, there is relatively little in the way of empirical data to assess uncertainty.

EPA's IEUBK model entails steady-state, i.e., stable, long-term distributions of lead among body compartments for body lead, derived in turn from stable intakes of lead. Factors that provoke abrupt changes in lead intakes from soils and other media, as might arise from heightened awareness and concerns about lead exposure and hazards to health of children by their parents and other care givers, can produce marked reductions in intake rates of dusts and soils. This can arise by such interventions as more attention paid to children's play behavior, limiting play to relatively clear areas, frequent washing of hands, etc. Such abrupt changes can also affect children's Pb-B levels and do so in a matter of days (Mushak 1998). Such abrupt changes cannot be modeled in a steady-state model, but rather require a physiologically-based pharmacokinetic (PB-PK) model. No such model, however, has been validated at extractive industry Western sites, unlike the extensive validation done for the IEUBK model.

There is some uncertainty in the Basin data about how soil lead ingestion rates for children can be estimated for scenarios beyond that of the residence: to neighborhood recreational soils, soils in rights of way, beach common use and other soil scenarios. This expanded view of uncertainty differs with the ages of children. Infants and toddlers are assumed to be largely confined to home or sites outside the home equally represented by a residential soil intake scenario. It is for increasingly older children that soils external to the residence are at issue. However, working in opposition to this uncertainty is the fact that soil ingestion rates are comparatively lower in older individuals and are likely within a relatively tighter range.

Dusts and Soil/Dust Ratios

One area of considerable uncertainty deals with the interplay of soil lead ingestion rates and ingestion of soil-derived exterior and interior dusts. Soil lead makes a major contribution to exterior dusts and household dusts through a variety of physical and environmental mechanisms. This is usually addressed through inferential statistical analysis, where the overall level of uncertainty is generally higher than if systematic experimental studies were done. By use of a form of multiple regression analysis, structural equation modeling researchers have been able to show that at many sites including Western extractive industry sites, soil lead contributes to dust lead and these dust lead intakes also produce associations with blood lead. It is now largely accepted that it is interior dust that is the proximate environmental pathway medium for lead exposures of infants and toddlers (Mushak 1998; Succop et al. 1998; USEPA 1996c).

All of the soil ingestion rate studies conducted to date have not experimentally stratified total soil rates into outside soils in the yard, playgrounds, etc., and soil-derived dusts around the entry and in household interiors. These include the studies of Calabrese and coworkers (Calabrese and Stanek 1995; Stanek and Calabrese 1995). These experimental designs were such this was not determinable. Soil-derived interior dusts are not merely interior soils, toxicologically, physically, or biokinetically. Dust particles are much smaller and presumably would be more bioavailable, tend to have higher concentrations of lead per unit mass, and differ on the time scale in terms of their stability as an exposure measure. Unremediated soil lead levels change slowly, while dust lead as an exposure metric can vary greatly depending on such variables as household dust distributions, household cleaning practices, where children encounter dusts, etc.

EPA's IEUBK model attempts to address the inter-relationship of yard/community soils and interior dusts derived therefrom by considering these media as linked via a ratio of 55% dust, 45% soil. The HHRA employed soil/dust lead ratios in both the default 55/45 mode and as a more stratified ratio of 40-30-30 interior dust, yard soil and community soil. This partition was developed through the use of structural equations analysis at the BHSS. However, for the Basin, it is not clear that the latter introduces less uncertainty into the input, despite the fact that this particular partitioning produce a concordance with the observed data similar to that at the BHSS. In common with refining of other input parameters, it is assumed that those ratios of soil and dust that produce closer agreement between predicted and measured blood lead levels are more representative of true child exposures. That may be an erroneous or misleading assumption where little assessment of the accuracy or reliability of the blood lead data has been done (Mushak 1998).

Food and Water Ingestion

Water lead levels are reasonably well known, given the preponderance of public supplies as water source for most of the Basin residents. Water volume intake rates are also reasonably well known as average values although climate in the Basin would indicate less water intake for much of the year than occurs in hotter climates. While there is some uncertainty about the range of water intakes and water lead levels owing to the presence or absence of lead-containing fittings, joint soldering, etc., overall lead intakes from water are comparatively less significant than those from soils and dusts. That's certainly the case for infants and toddlers, where oral exploratory activity greatly amplifies soil/dust lead intake.

A largely uniform, centralized food supply as any dietary lead source for the bulk of Basin residents constrains the uncertainty to variability in market basket lead testing results. In any case, background dietary lead for the base food supply is relatively low at the present time and relatively wide variability in this measure would contribute limited uncertainty to lead intakes from this pathway.

Garden crop lead intakes can be another matter. Garden crop data were gathered for the Basin since a number of residents had gardens. However, the use of garden crop intake parameters in this HHRA used very conservative EPA guidance values which served to likely overestimate to some extent lead intakes from garden crops. The garden crop lead intake scenario was employed in the HHRA in the context of incremental exposures, i.e., added intakes over the principal, baseline intakes of lead.

Lead intakes by Inhalation

Ambient air lead levels in the Basin at the time of measurements reported in this HHRA were quite low. Combined with ventilation rates appropriate for the different age bands of children, including infants and toddlers, one arrives at relatively low inhaled lead rates. Reentrained dusts in households where infants and toddlers spend most of their time would periodically occur with inside activity and presence of forced-air furnace units. However, this route's net input of lead relative to ingested interior dust lead would be relatively minor, even with considerable variability.

Lead Paint Intakes

Lead paint as a pathway, as is typical in most cases, can only be characterized in qualitative terms. Consequently, the amount of uncertainty and variability associated with lead intakes from this source in young children is principally inferred in comparative terms. That is, SEM or other regression analysis techniques are generally used to calculate associations with paint exposure blood lead and compared to the relative contribution of soil lead, the latter modeled as working both directly and indirectly through dusts. The relative crudeness of indices for lead intake from paint rule out its ready use for input to any of the biokinetic models estimating blood lead, including the IEUBK model.

Incremental Exposures

The above pathways largely described the baseline lead exposures as defined by applications of the IEUBK model in the modeling subsections of Chapter 6 of the HHRA. Incremental lead intakes from non-residential soils away from the home can significantly add to overall exposure. These incremental exposures are largely assessed indirectly as to the degree of uncertainty in the parameters by observing how such incremental intakes alter agreement between estimated and measured blood lead levels. Again, this assumes that the blood lead data used for comparison are reasonably accurate and reliable.

Coeur d'Alene Tribal Subsistence Scenarios

Lead exposures for tribal members who do not engage in any traditional subsistence activities likely approximate those for the rest of the Basin residents. There is some uncertainty as to how much traditional patterns of interactions with Basin contamination zones exist, do not exist, are strongly discouraged, or are not strongly discouraged. No evidence exists to conclusively show that such traditional or current tribal subsistence activities do not occur.

Intakes of lead by tribal members within the traditional and current subsistence exposure scenarios are assumed to be associated with potential future uses, as tribal cultural practices were abandoned in this area a century ago. This means that there are few checks on the extent of uncertainty or variability for the intake factors derived solely for tribal practices within the Basin.

However, there is a good technical grounding to the assumptions that some tribal-specific pathways are huge compared to the remaining residents in the Basin. The intake rates for various media are similar to those described for other tribal scenarios and seem to be reasonable. It cannot be said they are excessively protective absent any current evidence of that.

7.4.4 Uncertainty in Blood Lead Level Modeling

IEUBK Models

Uncertainties associated with blood lead level modeling are summarized in Table 7-6.

Baseline Blood Lead Levels Estimates. The HHRA applied the IEUBK model extensively for two categories of risk: 1) the estimation of blood lead level means and blood lead level distributions for multiple areas within the Basin and within baseline and incremental lead exposure scenarios, and 2) calculations of blood lead level means and distributions at various yard soil cleanup concentrations. All model runs were accomplished using both the community and batch mode of the IEUBK and the EPA Default and Box Models. For reasons discussed below, risk managers should favor the batch mode application in their considerations. There are arguments favoring application of both the EPA Default and Box Models.

In both the EPA Default and Box Model versions, national default recommendations were used for all assumptions for which no site-specific information was available. The development of those assumptions and the associated uncertainties are described in detail in other publications and are not repeated in this discussion. For the EPA Default Model, only site-specific media concentration data were used. All other parameters are those suggested by current guidance.

The Box Model was applied as it was used in the BHSS Five Year Review document (TerraGraphics 2000a) and was not "adjusted", or calibrated, to fit observed Basin blood lead data. The Box Model was developed through structural equation analysis of the last twelve years of blood lead and environmental exposure data collected through the course of BHSS cleanup. The Box Model does show a better concordance with observed data in the Basin and BHSS areas where residential exposures are dominant. The EPA Default Model significantly over-estimates blood lead levels in those portions of the Basin.

Community versus Batch Mode. All runs were accomplished in both the community and batch mode. The community lead exposure approach, where each of the areas in the Basin was characterized by geometric mean media-specific lead inputs to the model, gives a community-wide depiction of blood lead level mean and distribution. The second characterization of child exposures was the use of batch runs using available lead concentrations for each residential unit's media.

Use of the community mean input approach and subsequent estimation of community blood lead level means and blood lead level distributions is the least computationally and conceptually desirable of the various approaches that can be employed. The community approach subsumes too much uncertainty simply because it attenuates heterogeneity of lead exposures, and understates the most revealing depictions of blood lead distributions. For this reason, the IEUBK model's user manual (USEPA 1994a, b) discourages use of the model at this insensitive, gross level.

The batch run mode, where a blood lead level is calculated for each set of environmental input data for each residence, provides the most sensitive depiction of blood lead level and its distribution in the various communities. This approach also is in accord with user manual guidance. Risk managers should consider the results of the batch mode runs as more reliable than those produced in the community mode.

Soil and Dust Partition. The Box Model's 40:30:30 house dust, yard soil, community soil partition was derived through structural equation analysis at the BHSS. It differs significantly from the EPA Default assumption in the inclusion of a soil contribution from outside the home yard. Other studies have noted that area-wide and neighborhood soils are significant contributors to blood lead levels in a community setting. At the BHSS, community-wide soils were identified as the greatest contributor to blood lead as a direct source and as a large component of house dust. It is likely that effective remediation efforts will require attention to community-wide soil levels, as was necessary at the BHSS. As a result, the EPA Default Model would not be expected to accurately describe observed blood lead levels, if there was a significant intake from community soils that differed from the yard lead exposure. The EPA Default Model, however, might better reflect the exposures of young children that seldom leave the home environment.

Bioavailability. Two choices of bioavailability were made for the IEUBK runs the default value of 30% and a lower figure of 18%, previously found to give good agreement with blood lead level data at the BHSS. The choice of 18% is potentially problematic, as it was borrowed from the specific set of conditions observed at a potentially different exposure area, even though that area was within the Basin. The 18% figure reflects those variables and conditions inherent in the BHSS screenings, that differ from the screenings accomplished in the Basin outside of the Superfund Site. The 30% bioavailability value is potentially problematic in that several studies at western mining sites suggest this figure may be high. Bioavailability is discussed in more detail in Appendix O.

It is important to note that the derivation of the 18% bioavailability estimate for the BHSS assumed that there was no suppression of intake rates associated with educational and intervention efforts. All of the reduced dose-response indicated at the site was attributed to reduced bioavailability and not to reduced intake rates. There is evidence at the BHSS to suggest that intervention efforts have contributed to lower blood lead levels, likely through reduced intakes. As a result, the 18% bioavailability should be considered a minimum as it is applied. Similar model results could be obtained from equally credible assumptions of higher bioavailability and lowered ingestion rates. This is particularly important for risk managers to consider when using the model to predict future levels associated with risk reduction efforts.

Changes made to IEUBK input parameters to match observed blood lead levels should be made and interpreted with caution. Comparisons of observed versus blood lead level predicted by the EPA Default Model, show that the BHSS initially over-predicted by a factor of 2 times in 1989, but gradually converged toward default levels over the next 10 years as exposures decreased (TerraGraphics 2000a). An alternative interpretation of predicted versus observed blood lead trends at the BHSS is that the Box Model is more likely to over-predict blood leads for very high soil concentrations (> 2,000 mg/kg) and is less likely to over-predict blood leads for low soil concentrations (< 1,000 mg/kg) (Hogan et al. 1998). There is concern that applying the Box Model to the Basin may underestimate blood lead levels at lower concentrations. Since 1996, as lead concentrations dropped, the default bioavailability factor has accurately predicted blood lead levels at the BHSS (TerraGraphics 2000a). Conditions at Bunker Hill from 1996-1999 may more closely resemble the Basin than the period prior to 1996. Nevertheless, the Box Model does accurately describe mean blood lead levels and percent to exceed observations in those areas where community-wide residential soil lead concentrations are elevated.

The predictive value of the IEUBK Model depends on the representativeness of the environmental data to actual exposures (Hogan et al., 1998). This explanation relates to the results in the Lower Basin where residential lead levels are generally much lower than lead levels close to the Coeur d'Alene River. To the extent that children are exposed to elevated levels of lead remote from their homes, the Model will under predict their blood lead levels because it is under representing their exposure. Although this phenomenon seems most apparent in the Lower Basin (because homes are relatively cleaner than in other subareas), it may manifest throughout the site in the non-residential, incremental exposure scenarios. It may also be masked in areas where residences are moderately to severely contaminated with lead. If the remedy does not adequately address residential and incremental exposures, then remediated areas may exhibit the pattern apparent in the Lower Basin.

Geometric Standard Deviation (GSD). The GSD for blood lead distributions in human populations theoretically captures inter-individual variability in its physiological, behavioral, biokinetic and, to some extent, even exposure dimensions. A relatively small GSD adjustment can effect a considerable change in the upper tail of the log-normal blood lead distribution. No change in GSD from the EPA Default value was performed in these analyses for either model.

Incremental Blood Lead Levels. For inclusion of the incremental exposures in the IEUBK models, the same ingestion rates and exposure frequency and duration assumptions used for the non-lead metals were applied. As a result, the same uncertainty considerations apply. The most sensitive parameters in predicting blood lead increments among the models are ingestion rates, contact times, and bioavailabiltiy.

Site-specific Regression Models

Multiple regression analyses were run using various environmental inputs and calculating the robustness of statistical associations of each with measured blood lead level. There is uncertainty with how well the robustness of the associations were affected by how the environmental measures were gathered, and the appropriateness of the statistical models used. Interpretation of these results and reliance on the empirical relationships developed for future projections have inherent uncertainties.

For example, soil lead levels for use in either statistical or mechanistic, biokinetic models can have a direct impact on high-risk populations through contacting yard soils, and an indirect effect through generation of interior house dust levels. Because soil-based interior dust lead is derived from soil, this pathway is not competitive with a direct soil contribution but additive to it, and this requires a model to maximally depict such pathway relationships.

Statistical modeling by ordinary regression analysis was used to assess dose-response and soil to dust slope factors. This type of analysis runs the risk of missing the pathway-contributing variables of interior dust. In regression models developed with blood lead as the dependent variable, dust lead loading shows the strongest relationship with blood lead levels followed by independent effects of yard soil and paint lead. The effect of soil likely reflects direct contact with soil lead and such behavioral factors as time spent playing in bare soils, playing in sand boxes, the frequency of hand to mouth activities, etc. The importance of the paint condition variable likely reflects factors of home hygiene and socioeconomic status as well as lead source considerations. The major impact of both yard soil and the paint source variables is likely captured in the dust loading variable, as these are the ultimate sources of the lead.

Those equations in which interior house dust lead concentration is the dependent variable indicates that soil and paint are both independent sources of lead to house dust. The models all show strong statistical significance and are likely reasonable quantitative indicators of the relative significance of these sources. However, extending these models to future predictions of the effect of source reductions through remedial action should be done with care as the slopes developed include factors that may be independent of, or influenced in peculiar ways by, the remedial action.

These various pathway relationships can be quantified using structural equation modeling, a form of multiple regression analysis used at the BHSS (Succop et al. 1998, TerraGraphics 2000a). However, this analysis was not attempted with this data base due to a scarcity of paired blood-soil-dust mat-vacuum bag results. As a result the predictive equations discussed in the next section should be viewed with caution.

Adult Model for Lead

The USEPA guidance requires use of baseline blood lead concentrations that reflect no site-related exposures. The method is primarily used to assess risks from lead contaminated sites for people who do not otherwise have excessive lead exposures. However, some residents in the Basin may also have ongoing exposures to lead elsewhere in the Basin. The use of national baseline blood lead levels may underestimate risk for people with baseline blood lead concentrations that are elevated due to other exposures.

Subsistence Blood Lead Levels

Modeling of subsistence blood lead levels was not accomplished because the intakes estimated for these potential activities would exceed the practical limitations of available models. Human health risk assessments for lead among Basin residents entailed the use of annual blood lead screenings of children and adults and the use of the IEUBK model for descriptive estimates of blood lead averages and distributions. For tribal members, the model was not used nor are there any available blood lead screening data, notably for tribal children. Nevertheless, the exposures predicted for subsistence activities are great enough that blood lead levels exceeding 30 µg/dl can be expected for both children and adults.

7.4.5 Uncertainty Regarding Candidate Risk Reduction Activities

The risk reduction strategies discussed in Section 6 largely depend on the ability to accurately predict future environmental and blood lead levels based on projected remedial activities. The reliability of these estimates depends on the ability to describe current blood lead and environmental exposure levels, the applicability of those relationships in the future, and the effectiveness of the candidate remedial actions. The uncertainties in many of these considerations have been discussed above. These uncertainties include the representativeness of the observed blood lead surveys, the strength and applicability of the identified dose-response relationships, and the potential impacts of other sources either inadequately described or not quantified.

The overall analysis indicates that excessive levels of absorption are ongoing in both the upper and Lower Basin. Whether or not the available survey results overstate or understate the blood lead levels of non-participants, there is a clear need for risk reduction activities for, at least, those children with high blood lead levels. In the Upper Basin, house dust lead is the most important exposure source to children. House dust lead levels are influenced by soils and lead based paint. Analysis of the available data indicate both sources will require action to achieve acceptable house dust concentrations. Addressing only soil exposure will not resolve excessive intakes in homes with a significant lead paint risk. Conversely, lead paint stabilization will not sufficiently reduce house dust levels, as evidenced by homes with no lead paint problems having high dust lead concentrations.

Uncertainty in Risk Reduction Techniques

Intervention Programs. The first question with regard to the relative uncertainty is the specific type of risk reduction activity. The efficacy of intervention activities and long term reliance on methodologies to effect permanent behavioral changes are most uncertain. Reliance on education, and repeated warnings regarding parental attentiveness, as with personal and home hygiene, may be effective in the short term, but may lose their value as time goes on. The community as a whole has demonstrated little inclination for such programs by the failure to participate in screening surveys. Nearly one-third of children are currently in poverty. The coinciding socioeconomic problems that poor families deal with in raising their children, put a considerable burden on those families lacking in needed resources. These communities plan to revitalize their economies through recruitment of new industry. The continuing implementation of invasive public health intervention activities may deter investment in the area. This, in turn, will not help to resolve the poverty-related risk co-factors, making exposure more difficult to address.

Access Restrictions and Institutional Controls. Remedial techniques to restrict access to contaminated media vary in uncertainty. Secure well-maintained fencing, physical barricades or protective barriers restricting access to contaminated sites can be successful in eliminating exposure. However, there are incumbent maintenance obligations that must be accepted and carried out and an appropriate enforcement mechanism must be established to ensure compliance. These institutional requirements introduce a level of uncertainty depending on the cooperation of the affected parties. Access restrictions through signage, education and public cooperation to maintain awareness are less certain; the public has indicated some reluctance to accept and maintain signs in CUAs.

Cleanup Actions. Elimination of contaminated media and replacement with suitable clean materials offers the most certainty. However, the question of how clean is clean always presents uncertainty. With regard to risk reduction measures involving cleanup of contaminated environmental media, the greatest unknown in effectively remediating the upper Basin is how much will soil cleanup and paint stabilization reduce house dust lead levels. In the Burke/Nine Mile area, these exposures are exacerbated by children accessing contaminated neighborhood areas and waste piles. There is considerable experience in remediating these types of sites in the BHSS that can be used to reduce uncertainty in their effectiveness.

In the Lower Basin, there is evidence that exposures to sources outside the home environment are contributing to, or are largely responsible for, excess exposure. In the Lower Basin, these exposures will not be significantly reduced by residential cleanup. Protecting homes from flooding and development of clean recreational areas are candidate actions to reduce excessive exposures in the Lower Basin. These remedial activities offer significant engineering challenges and are subject to continual re-contamination by flooding. The uncertainty in these approaches are related to technical feasibility and the public's willingness to use clean areas and avoid unremediated recreational sites.

Uncertainty in Blood Lead Projections

Comparisons between observed and predicted blood lead level must be judged at both portions of the distribution:

1) central tendency (geometric mean)
2) high-end (percentage of children above 10 μg/dl)

The protectiveness of remedial strategies considers both central tendency and high end risk estimates for current and future conditions. Since 1994, USEPA policy is to control risks to individuals from lead associated with discreet residences as well as the aggregate risks to entire communities (USEPA 1994d, 1998f). A target proportion of 5 percent or less for a typical child exposed to a discreet residence above 10 μg/dl is the basis for determining target cleanup levels on Superfund Sites. Current USEPA Guidance recommends the use of IEUBK Model to best evaluate target cleanup levels for lead (USEPA 1994d, 1998f).

The analyses conducted in this assessment are consistent with that guidance. There is uncertainty, however, in the application of the models. All those factors discussed above should be considered including parameter uncertainty in the measurement of media contaminant levels and calculation of model inputs, in the selection of soil/dust partition and bioavailability, and in the comparisons to observed blood lead levels.

Aside from those many considerations, the brief sensitivity analysis conducted in Section 6 indicates the two most critical elements in projecting post-remedial blood lead levels. Those are 1) the selection of either the EPA Default or Box Model and 2) the projection of post-remedial house dust lead levels.

The analysis conducted in Section 6 suggests that the Box Model may be the more effective predictor of blood lead levels for the Basin. Results in the remedial program at the BHSS are testimony to the potential success of a similar approach in the Basin. However, this model relies on a reduced dose-response relationship developed from site-specific analysis of blood lead and environmental source relationships.

Adjusting the IEUBK Model based on paired environmental and blood data is a hybrid empirical approach to a mechanistic model. Empirical models describe direct and indirect relationships between measures of exposure and blood lead. By definition, empirical models describe observed relationships. They are descriptive of recent past conditions but may not be predictive of changed future conditions. The BHSS bioavailability value may not be reflective of baseline conditions to the extent that the 18% value reflects the sustained and intensive efforts of lead health intervention activities. Use of the Box Model to accurately predict blood lead concentration and select soil action levels in the Basin may be contingent upon a sustained effective Lead Health Intervention Program. The EPA Default Model results offer additional protectiveness, but that could come at a high price with little additional benefit if the Box Model assumptions are accurate.

The dust lead projections are empirically based on the site-specific regression analysis. The uncertainties associated with these models are discussed above. That the modeled relationships are similar to, and that the projections parallel, the results observed at the BHSS provides some comfort. Nevertheless, reducing house dust lead concentration is likely the most critical factor in bringing blood lead absorption to acceptable levels in the Upper Basin.

Uncertainty Due to Unaccounted Multiple Exposures

In view of the importance of reducing house dust lead levels in any remedial strategy, it is important to consider other factors that may influence this media. Lead paint abatement, control of fugitive dust sources, stabilization of waste piles or tailings accumulations where tracking may occur, street cleaning and washing, greening programs, cleaning curbs and gutters and installing storm-water infrastructure, and interior cleaning are all measures that could help reduce dustiness and dust lead content.

Several potential exposure pathways were not quantified in the HHRA. These were discussed in previous sections for other metals. Similar considerations apply for lead. Such exposures include consumption of whole fish from Lake Coeur d'Alene, inhalation of fugitive dust, ingestion of waterfowl and big game, consumption of locally raised beef cattle, breast milk and floodplain vegetation used by subsistence populations. Any significant exposure associated with these media, although unlikely, would add to blood lead levels.

Uncertainty in Sub-population Group Protectiveness

Children in the infant/toddler age band clearly have higher mean blood lead levels and probability to exceed health criteria associated with various soil lead cleanup levels. Risk managers may want to consider age-specific responses in evaluating cleanup strategies.

Uncertainty in Future Use Scenarios

Some of the most metals-polluted soils, sediment and vegetation occur in the river floodplain below Cataldo. It is likely that this area will experience significant pressure for land use change in the future, including residential expansion (both year-round and seasonal) similar to that now occurring in the Coeur d'Alene/Spokane area. Although much of the floodplain is presumably unavailable to residential growth because it is protected by government ownership/management, there are thousands of acres of private lands in or near the floodplain where growth could occur.

Additionally, the State and Tribe are in the final stages of approving and building a major recreational trail (the UPRR Right-of-Way) through the heart of the river corridor. There is potential for real or perceived conflict in the eyes of the public associated with warnings and restricted access in some areas and concurrent invitations to the public to use these improvements. The Coeur d'Alene Tribe has indicated a desire for a cleanup strategy sufficiently protective to eventually support subsistence activities. Risk managers may want to consider the possibility of expanded use of this area for recreational, subsistence and residential development in developing cleanup and risk reduction strategies.

Table 7-1
Summary of Geometric Means and Ratios of Chemical Concentrations in House Dust and Yard Soil

	Geometric Mean (mg/kg)				Ratio		
Chemical	**Floor Mat Dust**	**Vacuum Cleaner Bag Dust**	**Surface Soil[a]**	**Surface Soil[b]**	**Mat Dust/SS**	**Vacuum Dust/SS**	**Mat Dust/ Vacuum Dust**
Antimony	12.41	9.22	6.09	5.73	2.04	1.61	1.35
Arsenic	32.89	20.7	27.27	26.52	1.21	0.78	1.59
Cadmium	8.66	8.19	4.65	4.42	1.87	1.85	1.06
Iron	21,123.41	12,464.93	22,441.75	22,012.91	0.94	0.57	1.69
Manganese	1,040.96	558.76	1,073.99	1,045.1	0.97	0.53	1.86
Zinc	1,390.39	1,076.57	697.33	669.73	1.99	1.61	1.29

[a]Surface soil from yards with data from floor mat samples
[b]Surface soil from yards with data from vacuum cleaner bag samples

Notes:
Every home with a soil sample did not also have a mat sample and/or a vacuum sample.
Soil data were paired with mat data for all homes with mats and paired with vacuum data for all homes with vacuum data. Consequently, the means for surface soil paired with mats and surface soil paired with vacuums are different because the soil sample populations are different.

SS - surface soil

Table 7-2
Cadmium Concentrations in Vegetables and Soil

Sample Type	1983 PHD data, dry weight (mg/kg)[a]	1998 EPA data,[b] dry weight (mg/kg)
Carrots	19 Samples; mean = 4; range = 1 – 11	9 Samples; mean = 1.8; range = 0.3 – 4.7
Beets	7 Samples; mean = 6; range = 2 – 13	1 Sample; concentration = 0.6
Lettuce	10 Samples; mean = 12; range = 4 – 28	6 Samples; mean = 11; range = 3 – 28
Garden soil	20 Samples; mean = 7; range is 3 – 15	31 Samples; mean = 5; range is 1 – 36

[a]These results are from the Pinehurst area only (PHD et al. 1986). Smelterville and the Kellogg-Wardner-Page area were also sampled and generally had higher cadmium concentrations in soil and vegetables than Pinehurst. However, the Pinehurst samples were selected as potentially more representative of current conditions. The other two areas have been the subject of intensive remediation efforts.
[b]Data provided in Appendix F.

Table 7-3
Generic and Basin-Specific Elements of Uncertainty in Pb-B Data Gathering

Screening Event	Area of Uncertainty	Level of Uncertainty	Direction of Bias
Typical	Nature of screening: programmatic vs. health intervention, vs. single-shot	Potentially moderate to high absent programmatic structure	Typically lower Pb-Bs owing to attenuating effect of publicity, education, alarm, etc.
IDHW/ATSDR 1996	Reflection of Pb-B statistics in entire Basin	Moderate given level of participation	Potentially an underestimate absent statistical testings of screened vs. non-screened
Later 1997, 1998, 1999	Comparability of study or screening design with 1996 data	Moderate in comparison with 1996 results	Bias indeterminate over all 4 data sets

Table 7-4

Elements of Uncertainty in Environmental Lead Data Gathering and Assessment in The Basin

Pb Medium	Sampling	Main Areas of Uncertainty	Level of Uncertainty/ Bias
Yard soil	Variable across studies: single or subcomposite	Full reflection of high Pb areas and Pb distributions	Moderate/ underestimate
Dust	Personal vacuum cleaner bags or entry mats	Areas of home covered: relative inputs from yard soil	Moderate/ bias indeterminate
Community/other soils	Recreation, beach and waste pile sample testing	Relative contact times for variable age children	Moderate/ overestimate for infants and toddlers, likely overestimate for older children
Lead-based paint	Surface Pb by XRF + condition ranking: multiple measures	Largely qualitative testing; frequency of child contact vs. multiple Pb measures	Moderate/overestimate owing to multiple and/or maximum measures
Ground water	Monitor well sampling	Uncertainty for eventual use by public	High for future use scenarios
Surface water	Stirred water with sediment suspension	Likely ingestion with sediment at this loading	Moderate/ overestimate
Vegetables	Current garden crop samples: growth period unknown	Sampling across yards and within yards	Moderate to high/ bias indeterminate

Table 7-5
Elements of Uncertainty in Lead Exposure Data in the Basin

Pb Medium	Variable	Areas of Uncertainty	Level of Uncertainty/ Bias
Yard soil ingestion	Soil ingestion rate and at which sites	How much soil ingested daily?	Moderate/ bias indeterminate
Soil-derived dusts	Soil-dust ratios	% of total soil = dust?	For model, moderate/ likely underestimate using "Box" 40:30:30 dust -yard soil - community soil vs. 55% -45% model default
Food	Current diet Pb intake	Centralized vs. local/ ethnic food in diet	Overall, low impact/ bias minimal
Tap water	Daily water volume and total Pb intake	% first-flush vs. full-run samples	Overall impact low/ bias minimal
Inhalation	Ambient air or reentrained dust inhalation	Inside/ outside time ratios, high for dust inhalation	Overall impact low/ bias indeterminate
Lead paint	Multiple measures incl. maximum reading and median of readings + condition ranking	Qualitative, not quantitative assessment; which of multiple measures most valid?	Moderate to high/ analyses favor overestimating
Multimedia incremental Pb intakes	Non-baseline intakes, largely away from home	Amounts of intake for quite different scenarios	Moderate/ overestimate
Multimedia Coeur d'Alene Tribal scenarios	Intakes of Pb media under "subsistence" scenarios using published data	Extent of variance with regular residents theoretical; question of level of use of subsistence practice	Moderate to high, given theoretical scenarios/ bias indeterminate, but high overestimate with practice avoidance

Table 7-6
Elements of Uncertainty in IEUBK Modeling of Pb-B Levels in The Basin

Model Parameter	Areas of Uncertainty	Level of Uncertainty	Direction of Bias
Bioavailability, 18% vs. default	1) True extent of bioavailability difference vs. default 2) At 18%, how much lack of agreement is uptake differences vs. intake differences?	Relevance of 18% bioavailability used in "Box" to rest of Basin for various reasons, including child group differences, somewhat questionable	Likely an underestimate using blood lead data as reference for calibration
Soil/Dust mass ratios	True extent of partitioning difference vs. default, if any; limited validating of 40:30:30 ratio selected	Potentially moderate vs. default of 55% dust/ 45% soil	Pb uptake likely an underestimate since soil Pb uptake likely less than dust Pb; if higher soil fraction, lower net uptake
Choice of population testing a) community b) batch run of residential unit media Pb vs. estimated Pb-Bs	a) Predicted Pb-Bs via community mode are uncertain b) Predicted Pb-Bs via batch runs maximizes site-specific data at less crude estimating level, lower uncertainty	Community runs less certain than batch runs	Community runs minimize high Pb areas; bias the overall Pb-B distribution low
Pb cleanup levels vs. child age bands at different soil Pb values	Levels of adequate protection and preservation of "not more than 5% $\geq$ 10 μg/dl" guidance	Protective use of cleanup criteria at EPA's policy of 0-84 mo. age band uncertain for most vulnerable age group: infants, toddlers	Tabulated estimates of exceedances of 10 μg/dl higher for 9-24 mos. vs. 0-84 mos.